ANNUAL PROGRESS REPORT

Laboratory
Report No. 30

CLINICAL INVESTIGATION PROGRAM

30 SEPTEMBER 1994

DEPARTMENT OF CLINICAL INVESTIGATION

Fitzsimons Army Medical Center
Aurora, Colorado 80045-5001

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13. ABSTRACT *(Maximum 200 words)*

Subject report identifies these individuals who are conducting investigative protocols at Fitzsimons Army Medical Center. An abstract of each protocol giving abbreviated technical approach, obectives, and progress is presented.

Publications and Presentations by Fitzsimons Army Medical Center professional staff.

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ANNUAL PROGRESS REPORT

30 SEPTEMBER 1994

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
AURORA, COLORADO 80045-5001

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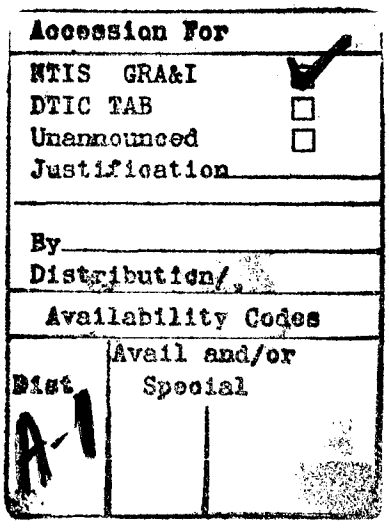

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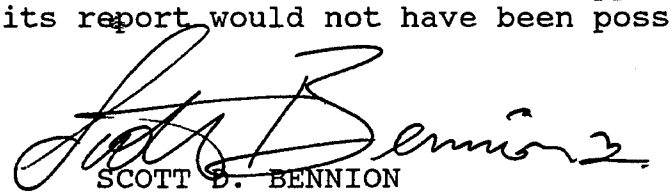
FOREWORD

This report highlights the research activities conducted by Fitzsimons Army Medical Center investigators during Fiscal Year 1994 as well as presentations and publications by FAMC professional staff.

The research protocols described in this report were conducted under the provisions of AR 40-38, Clinical Investigation Program, AR 40-7, Use of Investigational Drugs in Humans, AR 70-25, Use of Volunteers as Subjects of Research; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports, to insure the medical safety, well being, preservation of rights and dignity of human subjects who participated in these investigations. In conducting the research described in this report, the investigator(s) adhered to AR 70-18, The Use of Animals in DOD Programs and the "Guide for Laboratory Animal Facilities and Care", as promulgated by the Committee or the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

The Department of Clinical Investigation is grateful to the Center's Commanders, BG J. Sutherland Parker, and COL Arlene J. Zaloznik, and all of the professional and administrative staff for departments and directorates who have furthered the mission of Clinical Investigation Department at Fitzsimons through their cooperation and efforts. I should like to particularly recognize the outstanding work and dedication and wholehearted corroboration of all of the Services' within Clinical Investigation Department, the Assistant Chief, LTC Michael Lieberman, the Chief, Microbiology Service, LTC Richard Harris, the Research Protocol Specialist, Ms. Marcia Bilak, and Ms. Chris Montoya, Secretary, without whose assistance and support this year's progress and its report would not have been possible.



SCOTT D. BENNION
COL, MC
Chief, Department of
Clinical Investigation

UNIT SUMMARY

Clinical Investigation efforts by FAMC personnel in FY94 culminated in the publication of 207 articles and 160 presentations and lectures at national, international, and regional scientific meetings. As of 30 Sep 93 there were 313 ongoing protocols. Over the course of the year there were 388 active protocols. Seventy-five new studies were approved and 157 studies were completed or terminated. At the start of FY95 (1 Oct 94) there were 231 ongoing protocols.

Objectives:

To encourage the performance of clinically-oriented investigation by personnel assigned to the Fitzsimons Army Medical Center (FAMC). To aid in the planning, development, support, and execution of experimental clinical studies, both in patients and by directly related laboratory work, into the clinical problems of significant concern in the health care of members of the military community. To provide physician experience in research and investigative procedures by furnishing a highly educated and trained staff of specialists, laboratory facilities, administrative services and funding for: supplies, equipment, consultants, publications and reprints. To achieve continuous improvement in the quality of patient care by providing an atmosphere of inquiry, maintaining high professional standing and accreditation of advanced health programs.

The Clinical Investigation Program differs from Medical Research and Development in that the emphasis is on the health care problems existing in our patient populations, i.e., active duty, retired, and dependents and not solely on medical problems affecting combat readiness and the fighting strength. It is, by its nature, an integral part of the triad of patient care and medical education. It promotes and supports the finest ideals and traditions of Military Medicine and enhances the vitality of the teaching programs which in turn elevates the standard of medical care. The research program operates on the premise that all approved protocols will be supported to the fullest extent allowed by current funding. This concept allows for a larger number of physicians and ancillary personnel to participate in research rather than as in the grant system used elsewhere. This means that virtually every investigator is given a chance to pursue his research without having to compete for funds with "established" names in the field. Investigators are encouraged to seek extramural funding based on preliminary data obtained from in-house studies.

Technical Approach:

This support is carried out under the aegis of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; AR 70-25, Use of Volunteers as Subjects in Research; AR 70-18, Laboratory Animals, Procurement, Transportation, Use,

Care, and Public Affairs; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports, as amended; FAMC Reg 40-18, Institutional Review Committee. This Department provides guidance, assistance, and coordinates the FAMC program with higher headquarters.

Manpower: current authorized strength is outlined.

Description	Grade	MOS	Br	Req	Auth	Act	Name	Rank
C, Dept Clin Inv	06	60G8N	MC	1	1	1	Bennion, S.	COL
NCOIC, DCI	E7	91K40		1	1	1	Zahn	SSG
Research Prot Sp	09	0301	GS	1	1	1	Bilak	
Secretary	06	0318	GS	1	1	1	Montoya	
Nurse Specialist	11	0610	GS				Palestro	
C, Animal Res Svc	04	64C9B	VC	1	1	1	Corcoran	MAJ
NCOIC, ARS, DCI	E5	91T2R		1	1	1	Bowers	SSG
Animal Care Sp	E4	91T2R		1	1	2	Bayles	SSG
							Burgess	SGT
OR Nurse	10		GS				Wehba	
OR NCO, ARS	E5	91T2R		1	1	0		
Animal Care Foreman	04	5048	WS	1	1	1	Jones	
Animal Caretaker	06	5408	WG	1	3	3	Chase	
	05						Giese	
							Ferguson	
C, Biometrics and Research Design	09		GS		1	1	Damiano	
C, Cell Phys Svc	13	1320	GM	1	1	1	Jackson, R.	
Bio Sci NCO	E6	91K3R		1	1	1	Johnson, T.	SSG
Bio Sci Asst	E4	91K1P6		2	2	3	Schaphorst, J.	SGT
							Nystrom, S.	SPC
							Horton, H.	SPC
C, Immunology Svc	05	68T00	MS	1	1	1	Lieberman	LTC
Microbiologist	11	0403	GS	3	3	3	Lima	
							Hoyt	
							Meuhlbauer	
Med Technologist	09	0644	GS	1	1	1	Sachanandani	
C, Micro/Biochem	05	68A00	MS	1	1	1	Harris	LTC
Bio Sci NCO	E4	91K1P6		1	1	1	Sipple	SSG
Microbiologist	11	0403	GS	1	1	2	Paine	
							Andreatta	
Md Technician	07	0645	GS	2	2	2	Nelson	
							Revello	
Med Technologist	09		GS	1	1	1	Vacant	
Research Chem	11	1320	GS	1	2	1	Noble	

Description	Grade	MOS	Br	Auth	Req	Act	Name	Rank
C, Molecular Bio	13	1320	GS	1	1	1	Gutierrez	
Research Chem	11	1320	GS	1	1	1	O'Brien	

Funding

The OMA costs have not been itemized by protocol number because it is not feasible or practical to do so.

		FY 92	FY 93	FY 94
OMA	Civilian Personnel	1,067,960.	1,128,000.	882,929
	Contracts/Supplies	319,322.	306,000.	485,792
	Ceep Equipment	55,183.	61,000.	140,456
	Travel	9,624.	8,000.	8,000
OPA	MEDCASE	220,366.	132,000.	221,597

Personnel

	Required	Authorized	Assigned
Officers	6	5	4
Enlisted	13	12	9
Civilian	29	22	21

GRANTS for FY 94

(1) Prospective collection and banking of lymphocytes and clinical data on HIV infected individuals taking antiretroviral agents.

FY 93 $190,000.
FY 94 $190,000.

(2) Etiology and progression of acute muscle tension related low back pain occurring during sustained activity inlcuding combat training exercise. **Funded ended on September 1994**

(3) Use of body surface heat patterns for predicting and evaluating acute lower extremity pain among soldiers.
Funding ended on September 1994

NIH Grant - LTC Richard Sherman $18,728.12

Henry M. Jackson Foundation for th Advancement of Military Medicine: (HMJFAMM) Activity for FY 1994: $3,968.00

Facilitators of Applied Clinical Trials (F.A.C.T.) Activity for FY 1994: $23,407.19

There was no CRDA during FY94.

ANIMAL RESOURCES SERVICE
FY 94

The Animal Resources Service continued efforts to upgrade and improve the care provided to the laboratory animals assigned and to the support provided the medical center staff. This service provides regular training for various surgical skills (soft and hard tissue, gross and micro-surgery) and perioperative requirements (intubation training). Research efforts have continued with significant support to the orthopedic residency program, ophthalmology, otolaryngology, dermatology, and rheumatology.

Service personnel at year-end included 1 Laboratory Animal Veterinarian, 3 Animal Care Specialists, 1 Surgical Nurse, 1 Animal Facility Manager, and 3 Animal Care Providers. One Hahnemann University graduate student, Ms. Bisque Jackson, participated in a 4 month clerkship. During the year Mr. John Ferguson, Animal Care Provider, joined the ARS staff. SFC Vickie Barrett PCS'd to Korea and SGT Pennylynn Zobrist completed her enlistment. Animal Care Specialists, SSG James Bayles and SGT Kathleen Burgess joined ARS in January.

The Animal Care and Use Program was reviewed by the DoD IG as part of the DoD-wide fact finding effort. No deficiencies in the program were noted. Four "commendable" practices were identified in the ARS program and were recommended for adoption throughout the DoD.

The Service participated in the first comprehensive report to Congress of DoD research and training activities using animals.

MAJ Corcoran and Mr. Jones attended the 44th AALAS Annual Meeting in Nashville, TN in November. MAJ Corcoran, SSG Bowers, Mr. Jones, Ms. Chase, and Ms. Giese attended the Annual Clinical Investigation Postgraduate Short Course in San Antonio in June.

MAJ Corcoran, SSG Bowers, SSG Bayles, SGT Burgess, Mr. Jones, Ms. Chase, Ms. Giese, Mr. Ferguson, and Ms. Jackson attended the AALAS Mile High Branch Annual Meeting in Aurora in April. The Service made two presentations at the meeting and one received the Best Presentation Award. MAJ Corcoran is the president-elect of the organization and Ms. Geise serves on the board of directors.

MAJ Corcoran participated in the "Information Requirements of the Animal Welfare Act" workshop in Bethesda, MD in September.

Publications and presentations made by Service personnel are listed elsewhere in this report.

IMMUNOLOGY SERVICE
FY 94

The Immunology Service, Department of Clinical Investigation, provides clinical immunology laboratory support and performs basic and clinical immunology research. Studies of both cellular and humoral immunity are conducted. Major areas of emphasis include flow cytometry, antigen and antibody analysis by enzyme-linked immunosorbent assays (ELISA), and functional studies of immunocompetent cells, such as mitogen and antigen stimulated lymphocyte transformation assays, opsonophagocytosis (bactericidal) assays on neutrophils, and natural killer (NK) cell cytotoxicity assays. Flow cytometry is used for lymphocyte immunophenotyping in HIV and other immunodeficient and autoimmune patients, leukemia and lymphoma typing, and DNA and cell cycle analysis in breast cancers. Also, cells from selected patients cultured in vitro with various mitogens or cytokines are analyzed for the expression of "activation" or 'memory cell" markers by flow cytometry, and for the production of immunoglobulins or cytokines by ELISA. In addition, various other immunochemical procedures are performed, ' such as electrophoresis and immunoblotting of antigens and antibodies ("Western blots") in specimens from autoimmune patients and analysis of serum proteins by rate nephelometry.

Currently, the Immunology Service is actively supporting protocols originating from the Allergy/Immunology, Dermatology, Gastroenterology, and Pulmonary Services, as well as the Departments of Surgery, Primary Care, and Clinical Investigation.

CLINICAL BIOMETRICS AND RESEARCH DESIGN SERVICE
FY 94

Orthopedic and General Surgery residents rotate through the Service as part of their regular training programs, Each resident spends two 2-week rotations learning clinical research design, statistics, computer and data processing. They also plan, write, and initiate a research project thus allowing them to become familiar with the specifics of managing a research protocol. LTC Sherman presented formal courses in both research design and biofeedback as part of pain management.

The VA funded study examining the reliability of pain reporting by patients was completed and the data is currently being analyzed. Also, the ambulatory recording study investigating low back pain among soldiers at Ft. Carson is completed and in the data reduction phase. LTC Sherman's studies examining relationships between muscle tension and headaches (tension and migraine) are completed at FAMC and data analysis is expected by the end of the year.

Biofeedback for Pain: A Multi-practitioner Outcome Study, A NIH Supported study, started in February 1994 with the hiring of a research coordinator. The study was well advertised resulting in sixty-nine biofeedback practitioners actively participating. Each practitioner has been able to recruit ten to twelve patients who meet the entrance requirements, this should allow a sufficient number of low back pain subjects to answer the study's main goals. At this time, it appears that there will be an insufficient number of orofacial pain patients participating to address the effectiveness of biofeedback with these patients. This study has relocated to MAMC.

Pilot studies are being performed to determine the value of using pulsing electromagnetic fields (PEMFS) to (a) speed healing of tibia] and metatarsal stress fractures and (b) reduce pain and swelling after hard and foot surgery. This work is supported by both the US Army and the Diapulse Corporation of America. Two upcoming studies will be funded by the Defense Women's Health Research Grants-. 1) Evaluation of the Performance Impact and Treatment of Exercise Induced Urinary lncontinence Among Female Soldiers, and 2) The Non-Invasive Detection and Characterization, Treatment and Potential Prevention of Anal Incontinence in the Parous Active Duty Female Population.

CELL PHYSIOLOGY SERVICE
FY 94

Autoimmune blistering skin diseases involve antigen components found either side of the dermal-epidermal junction or basement membrane zone (BMZ). Even with direct and indirect immuno-fluorescence staining, clinical differentiation of certain blistering diseases is sometimes difficult. Ultrastructural evaluation of skin BMZ using gold-antibody conjugated nanoprobes and transmission electron microscopy have allowed localization of sites involving these disease-associated antigens. Both 1.4 and 5.0 nanometer (diameter) gold-conjugated antibodies to laminin, Type IV collagen, GB3 have been investigated. Smaller sized probes combined with silver enhancement of sectioned adult or neonatal skin samples has demonstrated positive results. These findings will validate procedures which may have potential use in diagnosing autoimmune type diseases., specifically a split-skin technique. Separation of the epidermis from the dermis of a collected skin specimen (split), when combined with immune-fluorescence staining may improve current clinical methods for identifying certain blistering skin disorders. Results from this study (91-125) will be presented in a symposium next spring.

The diagnostic value of using immunocytochemical stains in identi-fying particular skin tumors or disorders is continuing under protocol 134-91. Epidermal cells including keratinocytes, fibroblasts and melanocytes have been isolated from normal human skin and cultured singly or in combination to study the expression of certain disease-associated antigens. By altering culture

conditions to mimic various pathologic environments, preconfluent, cultured keratinocytes are utilized to simulate acantholytic round cell carcinoma and will be compared with post-confluent keratinocytes (normal state) for binding antigens, vimentin and cytokeratin. Melanocytes grown individually or in combination with keratinocytes are being investigated for the expression of HMB-45, an antigen associated with melanocytes in malignant melanomas. Immunology Service is collaborating some of these projects by evaluating antibody binding using Fluorescence Assisted Cell Sorting (FACS) . Preliminary data has shown that antigens thought to be only expressed in pathologic states are also expressed in normal cells under certain conditions.

CPS's collaboration with the Neonatology departments of FAMC and UC Health Sciences Center in developing human and ovine placental trophoblast cultures to facilitate <u>in vitro</u> study of fetal metabolism continues. Cultures of normal human and ovine trophoblasts has already been established. Studies are in progress which will evaluate laboratory methods to produce cell isolates with greater purity and yields. A number of projects are planned for the coming year to characterize trophoblast metabolic requirements.

MICROBIOLOGY/BIOCHEMISTRY SERVICE - FY 94

A study with the Allergy service is comparing the efficacy of various extraction procedures for pollen allergens used in skin testing. A comparison of extraction procedures using Russian thistle pollen was recently completed and a manuscript has been prepared for journal submission. A study examining microbial contamination of pollen extracts is being completed.

A protocol examining Hepatitis C infections in military families is continuing. The Microbiology and Molecular Biology Service are jointly investigating genetic variation of the Hepatitis C envelope hypervariable region in HIV co-infected patients.

An HIV natural history study in collaboration with FAMC Infectious Disease service and the Department of Diagnostic Retrovirology at WRAIR is providing information on the development of AZT resistance at the molecular level in HIV-infected patients. The patient data base has been used to analyze the impact of AZT therapy on disease progression at various stages of HIV disease. An analysis of patterns of AZT resistance is being conducted on HIV strains of patients samples within 1 year of seroconversion.

The Microbiology Service and the Inpatient Pediatric Service are continuing a protocol examining γ-interferon therapy of Group B Streptococcal sepsis in neonatal rats. A survival study of combinations treatment with γ-interferon and penicillin has recently been completed.

The Biochemistry Service has been combined with the Microbiology Service due to a loss of the service chief and technical personnel. The service is supporting a study of urine and serum arsenic concentrations following melarsoprol therapy in a patient with trypanosomiasis.

The Biochemistry laboratory has recently completed several studies including a protocol supporting the Endocrine service examining bone density in thyroid extract-treated patients and a study supporting the Pulmonary service examining the effect of recombinant growth hormone on pulmonary function in patients with COPD.

MOLECULAR BIOLOGY SERVICE - FY 94

The assigned staff of the Molecular Biology Service are Dr. Anthony G. Gutierrez, Chief, GS13, Ph.D. in Molecular Genetics, and Ms. Judith O'Brien, Research Associate, GS 11, Medical Technologist/Chemist. The Service benefitted from the long term part-time intradepartmental assignment of Cindy Andreatta, GS9, from the Microbiology Service. Sgt Jefrey Sipple has also been assigned to work in Molecular Biology part-time.

Dr. Gutierrez attended Applied Biosystems' course on "Sequencing Difficult Templates" May 1-3 in Foster City , California. We have subsequently established procedures for sequencing the E2/NS1 hypervariable region of HCV ant the Reverse Transcriptase gene of HIV. These sequence data are currently under analysis for subsequent publication.

Dr. Gutierrez, Ms. O'Brien and Ms. Andreatta attended the annual American Society for Microbiology Meeting in Las Vegas, May 23-27.

In January and April beta site testing was done on new lots of Chiron HCV RNA reagents. The data were used to modify software algorithms and adjust control values.

Ongoing Protocols:

#91-106: A Randomized, Controlled Trial of Interferon Alpha and Thymosin Alpha-I in Patients with Hepatitis C Antibody Positive Chronic Active Hepatitis. Dirk Davis, MAJ, MC, Principal Investigator, Kenneth E. Sherman, MD, Associate Investigator. Viral loads of hepatitis C were measured at 0 and 26 weeks using the Chiron branched DNA chemiluminescence method. PCR was also done on these samples for detection only. Primers were prepared for amplification of the non-structural NS-5 region of HCV. Sequencing of this region is being done to determine the genetic strain(s) of the virus to determine whether there is correlation between viral genotype and patient response to treatment.

Detection of Measles RNA in Intestinal Tissue Samples from Patients with Crohn's Disease by a Polymerase Chain Reaction Assay. Scot Lewey, MAJ, MC, Principal Investigator; Kenneth E.

Sherman, MD and John Singleton, MD, Associate Investigators. Primers were synthesized and reverse transcription and PCR methods were optimized for detection of measles virus in colon. Biopsy samples of colon tissue are being collected from patients with inflammatory bowel disease. Dr. Erik Mondrow of St. Joseph's Hospital, a colleague of Dr. Lewey, spent the month of August in this laboratory developing a PCR procedure for detection of Mycobacterium paratuberculosis, which causes Johne's disease in ruminants and has been implicated in Crohn's disease as well.

#91-300: Hepatitis C in Pregnancy: Viral Titerrs and Thymosin Levels. Kenneth E. Sherman, MD, Principal Investigator; Judith O'Brien, DAC,. Associate Investigator. Samples are being collected at the University of Colorado Health Sciences Center.

Use of a Degenerate, Nested Primer PCR Technique for Non-Invasive Detection of Anogenital Human Papillomavirus in Males. Clive Daniels, CPT, USAF, MC, Principal Investigator; Anthony Gutierrez, PhD and Judith O'Brien, DAC, Associate Investigators. Primers were synthesized and PCR method optimized for detection of HPV. Dr. Daniels is collecting samples at the US Naval Medical Center, San Diego, CA, to send to FAMC for PCR.

Sequencing of E2/NSI Hypervariable Region of Hepatitis C: Cindy Andreatta, Dr. Harris.

A DNA Polymerase Assay for Hepatitis B in Prairie Dogs , a possible model system for the study of infectious HBV in humans, has been under development since the beginning of the year by LTC Harris and Sgt Jeff Sipple.

In June, Dr. Gutierrez entered into a collaboration with Harry Drabkin, MD and Ferenc Boldog, Ph.D. of the University of Colorado Health Sciences Center to sequence a region of human chromosome 3 implicated in breast cancer. Approximately 10 Kb of DNA was sequenced for matching analysis to tumor suppressor genes in the GenBank database.

Also in June, Dr. McDermott, Chief of the Endocrinology Service, had clones from a thyroid tumor cell line sequenced in aid of a collaboration he has with Dr. David Gordon of the Endocrinology Dept. at UC HSC.

Throughout the year, Capt. Miguel Quintana, William Irwin, and other personnel from the Army Environmental Health Sciences Agency have worked in the Molecular Biology laboratory. They received training on the synthesis of primers, DNA extraction and PCR for the detection of Borrelia burgdorferi and other pathogens in insect vectors. In April, an entomologist and two technicians from Fort McPherson, GA, spent a week in Molecular Biology for a short course on PCR. In September, Dr. Dorothy Fier, Professor of Entomology at St. Louis University, also visited this laboratory for PCR instruction.

DEPARTMENT OF CLINICAL INVESTIGATION

ANIMAL RESOURCES SERVICE

Training Support Summary: FY 94

One exercise was conducted in "Resuscitation of Newborn" for the American College of Obstetricians and Gynecologists/Indian Heath Service Postgraduate Course in Obstetrics, Gynecology and Neonatology. Forty physicians, nurse practitioners, and midwives received four hours of training in methods of resuscitation and endotracheal intubation, using thirteen ferrets and requiring fourteen hours of support by Animal Resources Service personnel, administering and monitoring anesthetic and cleanup. The ferrets were recovered and returned to the colony for re-use.

Fifteen rats were utilized in support of microsurgery training in the re-anastomosis of small vessels, providing thirty hours of training for four staff surgeons and two fellows from Plastic Surgery Service. Support of this training by Animal Resources Service personnel totaled sixty hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and sterilization.

Twenty-eight rats and four rabbits were used in support of microsurgery training in the reanastomosis of small vessels, providing sixty-four hours of training for a total of twelve staff surgeons and residents from the Orthopedic Surgery Service. Support of this training by Animal Resources Service personnel totalled one hundred-twenty-eight hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and sterilization.

A total of three ferrets, nine goats, nine guinea pigs, six rabbits, and three rats were utilized for the training of Animal Resources Service personnel. Twelve animal care personnel received twenty-five hours of in house training in husbandry, endotracheal intubation, restraint and phlebotomy techniques.

A total of two pigs were utilized in support of training of bronchoscopic techniques, providing four hours of training for two residents from Otolaryngology Surgery Service. Support of this training by Animal Resources Service personnel totalled ten hours, monitoring anesthesia, cleanup, and instrument cleaning and sterilization.

A total of thirteen pigs were utilized in support of training of laparoscopic and laparotomy techniques, including procedures on ureters, bladders and bowel, providing sixty-five hours of training for twenty residents from Gynecology Service. - Support for this training by Animal Resources Service personnel totalled ninety one hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and sterilization.

A total of two pigs were utilized in support of training of laparoscopic techniques, providing thirty-six hours of training for twenty residents from General Surgery Service. Support for this training by Animal Resources Service personnel totalled sixty hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and sterilization.

Cost of Training

Ferret Intubation
Pig Bronchoscopy
Pig Laparoscopy and Laparotomy
Pig Laparoscopy
Rabbit Microsurgery
Rat Microsurgery
In House Training
TOTAL

$2.00/animal x 13 animals = $26.00 $0.00/animal x 2 animals = $0.00 $240.00/animal x 13 animals = $3120.00 $190.00/animal x 4 animals = $760.00 $50.00/animal x 4 animals = $200.00 $24.00/animal x 43 animals = $1032.00
Total for all animals used = $25.00
$5163.00

Summary of Graduate Medical Education and Staff

During the school year 93-94 there were 10 Residency Programs, 9 Fellowship Programs, and 5 Internships. Thirty-four residents participated in 55 clinical investigation protocols. Fifteen fellows participated in 41 protocols. Eight fellows in Allergy-Immunology and Plastic Surgery participated in training protocols using animals. A total of 54 residents in Dermatology, General Surgery, Obstetrics-Gynecology, Orthopedic Surgery, Otolaryngology, Pediatrics and Urology participated in training protocols using animals. Ninety-one hospital staff (Medical Corps) held 263 protocols during FY94.

HUGH MAHON LECTURESHIP AWARD COMPETITION - 1994

This student research award was established in 1950 and honors the late Colonel Hugh W. Mahon, MC, USA, Retired, who was Chief, Department of Pathology, Fitzsimons Army Medical Center, for 12 years. The lectureship consists of the presentation of papers judged best from among those submitted by officers in training status at FAMC.

This year the Hugh Mahon Lectureship Award Competition was divided into the categories of literature reviews/case reports (13) and Residents'(13) and Fellows' (4) studies for a total of 30 submissions. In 1993 there were 28 submissions: in 1992, 38 submissions; in 1991, 34; in 1990, 36; in 1989, the largest with 41; in 1988, 23; and in 1987, 18.

Judging was done by the members of the FAMC clinical teaching staff and a panel of distinguished university and community professors, B. Eiseman, M.D., Professor Emeritus, University of Colorado Health Science Center, Robert Gibbons, M.D., Program Director, Internal Medicine Residency Program, St. Joseph's Hospital, and Harold Vogel, M.D., Chief of Neurosurgery, Denver General Hospital. Manuscripts were scored on originality and medical significance, experimental design, presentation and interpretation of data, and literary quality.

The first and second prize winners were chosen from among the finalists in the Residents' and Fellows' categories based on the presentation and question-and-answer period during the Hugh Mahon Lectureship Conference.

The finalists for 1994 are as follows:

Residents' Research

1st place: Carpal Ligamentous Injuries Associated with Fractures of the Distal Radius. John Reister, CPT, MC, Orth Surg.

2nd place: Comparison of Three Devices Used for Postoperative Autologous Blood Transfusion. Steven Friedel, CPT, MC, Orth Surg.

Fellows' Research

1st place: The Prevalence of Dermatophagoides Mite Antigen in Colorado Homes Utilizing Central Evaporative Coolers. Amy Ellingson, CPT, MC, All-Imm/Med.

2nd place: Reactivity to Booster Pneumococcal Vaccine. Roberto Rodriguez, MAJ, MC, All-Imm/Med.

Case Reports/Literature Review: A 39 Year Old Man with Chronic Hepatitis. Steven Lawrence, MAJ, MC, Gastro/Med.

PUBLICATIONS - FY94

C = Protocol Related

OFFICE OF THE DEPUTY COMMANDER

Runkle GP and Zaloznik AJ: Malignant melanoma. American Family Physician 49:91-98, 1994.

Zaloznik AJ: Do black females with breast cancer present at a more advanced stage than caucasian females? Breast CA Research Treat **Abstract** 188: 177, 1993.

Zaloznik AJ: Breast cancer stage at presentation: A comparison of four racial groups. Proc ASCO:162, 1994.

Zaloznik AJ: Unproven (Unorthodox) cancer treatments. Cancer Practice 2:19-24, 1994.

Zaloznik AJ: Retention of internal medicine physicians in the U.S. Army. Military Medicine (to be published in June, 1994 issue).

DEPARTMENT OF MEDICINE

Gates RH: Infections in diabetes. Submitted, Endocrinology Secrets, 1994.

ALLERGY/IMMUNOLOGY SERVICE

Dyer PD: Late-onset angioedema after interruption of angiotensin converting enzyme inhibitor therapy. J Allergy Clin Immunol 1994;93 (5):947-8.

Ellingson AR, Ledoux BS, Weber RW. The Prevalence of dermatophagoides mite allergens in Colorado homes utilizing central evaporative coolers. J Allergy Clin Immunol 1994;93:179 **Abstract. C**

Ellingson AR, Ledoux BA, O'Connell MA. Goat allergy in a laboratory animal worker with guinea pig sensitivity. Ann Allergy 1994;72:63 **Abstract.**

Freisen CD, O'Connell MA, Dyer PD, and Schkade PA. Latex induced asthma in a dental assistant. Submitted to Journal of Allergy and Clinical Immunology.

Kumar SA, Lester MR, Bratton DL. KID (keratosis, ichthyosis, deafness) syndrome associated with elevated sweat chloride. Submitted to Annals of Allergy.

Kumar SA, Spaulding HS, Sutherland RS, Schkade PA. The effect of chlorpheniramine maleate on urination in men with symptomatic benign prostatic hypertrophy. Submitted to Annals of Internal Medicine. **C**

Kumar SA, Larsen LV, Ledoux BS, Schkade PA. Delayed anaphylactic reaction to banana. Submitted to Annals of Allergy.

Kumar SA, Spaulding HS, Sutherland RS, Schkade PA. The effect of chlorpheniramine maleate on urination in men with symptomatic benign prostatic hypertrophy. J Allergy Clin Immunol 1994;93:177 **Abstract. C**

Kumar SA, Larsen LV, Ledoux BS, Schkade PA. Delayed anaphylactic reaction to banana. Ann Allergy, 1994;72:68 **Abstract.**

O'Connell MA, Christopher LD, Ranlett RD, Craig DB, Guill MA. Stevens-Johnson syndrome associated with disseminated varicella. Ann Allergy 1994;72(1):70 **Abstract.**

O'Connell MA, Sklarew PR, Goodman DL. The spectrum of paradoxical vocal cord motion in the ambulatory setting. Submitted to Annals of Allergy, revisions sent to Editor August 1994.

O'Connell MA, Pluss JL, Schkade PA, Henry AR, Goodman DL. Woodtrimmer's disease in a tractor driver. Submitted to Journal of Allergy and Clinical Immunology.

Rodriguez R, Graham L, O'Connell MA, Spaulding HS. Foreign body aspiration: a masquerader of asthma. Ann Allergy 1994;72:77 **Abstract.**

Schkade PA, Routes JM. Hypersensitivity pneumonitis in a patient with hypogammaglobulinemia. J Allergy Clin Immunol 1994;93(1):300 **Abstract.**

Schkade PA, Goodman DL, Weber RW. Evaluation of 210 patients referred for chronic urticaria and angioedema. Ann Allergy 1994;72(1):97 **Abstract.**

Spaulding HS, Sutherland RS, Sklarew PR, Punja MK, Thrasher JB, Vaughan TR, Donatucci CF. Effect of terfenadine on urination. Ann Allergy 1994;72 (5):441-5. **C**

Westbrook TG, Dyer PD. Hay associated anaphylaxis. Ann Allergy 1994;72:65 **Abstract.**

CARDIOLOGY SERVICE

Dorogy ME, Hoots S, Cameron RW, Davis RC: Clinical and angiographic correlates of normal creatine kinase with elevated MB isoenzymes in

suspected acute myocardial infarction. Submitted, Am J Cardio, 1994.

DERMATOLOGY SERVICE

Battafarano DF, Combs JA, Enzenauer RJ, Fitzpatrick JE: Chronic septic arthritis caused by Borrelia burgdorferi. Clinic Orthopaedics and Related Research. 297:238-241, 1993.

Demidovich CW, Kornfeld BW, Gentry RH, Fitzpatrick JE: Deep dermatophyte infection with chronic draining nodules in an immunocompromised patient. Submitted, Cutis, 1994.

Fitzpatrick JE, Schleve MJ: Geriatric dermatology. Submitted, Textbook, Geriatric Medicine, Blackwell Scientific Publications, 1994.

Fitzpatrick JE: Adipose hypertrophics and neoplasms and muscular neoplasms: Pathology. Chapter, W.B. Saunders Company, 1994.

Fitzpatrick JE: Cutaneous manifestations of diabetes mellitus and thyroid disease. Submitted, Endocrinology Secrets, Hanley & Belfus, Inc., 1994.

Fitzpatrick JE: Acrodermatitis cateropathica. Submitted, J Cutaneous Pathology, 1994.

Fitzpatrick JE, Golitz LE: Unusual tumors. Submitted, Dermatologic Surgery, Second Edition, 1994.

Fitzpatrick JE: Dermatophyte infection with chronic draining nodules in an immunocompromised patient. Submitted, Cutis, 1994.

Johnson R, Jackson R, Bennion SB: The effect of toxic epidermal necrolysis and erythema multiforme major patient's sera on human keratinocyte viability in culture. Clinical Research 42:11 A, 1994.

Johnson R, Fitzpatrick JE, Hahn DE: Calcinosis cutis following electromyographic examination. Cutis 52:161-164, 1993.

Leibold AM, Bennion S, David-Bajar K, Schleve MJ: Occurrence of positive immunofluorescence in the dermo-epidermal junction of sun-exposed skin of normal adults. J Cutan Pathol 21:200-206, 1994.C

McGovern TW, Bennion SD: Palmar purpura; an atypical presentation of childhood dermatitis herpetiformis. Submitted Ped Dermatology, 1994.

McGovern TW, Gentry RH: Spiny keratoderma: case report, classification and treatment of music-box spine dermatoses. Submitted, Cutis, 1994.

Whang K, Middleton K, Bennion SB, David-Bajar K, et al: Differential roles for keratinocyte apoptosis in photosensitive lupus erythematosus. J Invest Dermatol 102:63 4, 1994.

ENDOCRINE SERVICE

Alex NH, Georgitis WJ, McDermott MT: Effective management of ectopic ACTH syndrome with spironolactone. (Submitted to The Endocrinologist 8/15/94).

Georgitis WJ: Retrospective comparison of the lipid lowering efficacy of Lovastatin and Provastatin. Submitted, Clin Pharma & Therapeutics, 1994.

Georgitis WJ, McDermott MT, Kidd GS: An iodine load from water purification tables alters thyroid function in man. Military Medicine 158:794-7, 1993. **C**

Lemar HJ, Georgitis WJ, McDermott MT: Thyroid adaptation to chronic tetraglycine hydroperiodide water purification tablet use. J Clin Endocrinol Metab (in press). **C**

McDermott MT, Perloff JJ, Kidd GS: The effects of mild asymptomatic primary hyperparathyroidism on bone mass in women with and without estrogen replacement. J Bone Min Res 9:509-14, 1994. **C**

McDermott MT, Perloff JJ, Kidd GS: A longitudinal assessment of bone loss in levothyroxine suppressed benign thyroid disease and thyroid cancer (submitted) 1994. **C**

May KP, West SG, McDermott MT, Huffer WE: The effect of low dose methotrexate on bone metabolism and histomorphometry in rats. Arthritis Rheum 37:201-6, 1994. **C**

Merenich JA, Georgitis WJ: Trial of pentoxifylline for diabetic impotence. Diabetes Care (in press). **C**

Perloff JJ, McDermott MT, West SG, Rubin RL: Lovastatin induced antinuclear antibodies (submitted) 1994. **C**

Simcic KJ, Georgitis WJ, McDermott MT, Carter T: Spontaneous remission of Cushing's syndrome caused by asymptomatic infarction of a pituitary macroadenoma (submitted) 1994.

BOOKS AND BOOK CHAPTERS:

Asp AA: Thyroid Cancer. In: McDermott MT, ed. Endocrine secrets. Philadelphia: Hanley and Belfus (in press).

Asp AA: Autoimmune polyglandular endocrinopathies. In: McDermott MT, ed. Endocrine secrets. Philadelphia: Hanley and Belfus (in press).

Asp AA: Multiple endocrine neoplasia. In: McDermott MT, ed. Endocrine secrets. Philadelphia: Hanley and Belfus (in press).

Asp AA: Primary aldosteronism. In: McDermott MT, ed. Endocrine secrets. Philadelphia: Hanley and Belfus (in press).

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Georgitis WJ: Endocrine syndromes under paraneoplastic syndromes. In: Wood ME, ed. oncology secrets. Philadelphia: Hanley and Belfus.

Georgitis WJ: Menopause. In: McDermott MT, ed. Endocrine secrets. Philadelphia: Hanley and Belfus (in press).

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Georgitis WJ: Thyroid nodules and goiter. In: McDermott MT, ed. Endocrine secrets. Philadelphia: Hanley and Belfus (in press).

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McDermott MT. Pituitary tumors and adrenal carcinoma. In: Wood ME, ed. Hematology/oncology secrets. Philadelphia: Hanley and Belfus, 325-8, 1994.

McDermott MT. Carcinoid syndrome and pancreatic islet cell tumors. In: Wood ME, ed. Philadelphia: Hematology/oncology secrets. Hanley and Belfus, 328-30, 1994.

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McDermott MT. Osteoporosis. In: McDermott MT, ed. Endocrine secrets. Philadelphia: Hanley and Belfus, 1994 (in press).

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McDermott MT. Carcinoid syndrome. In: McDermott MT, ed. Endocrine secrets. Philadelphia: Hanley and Belfus, 1994 (in press).

McDermott MT. Inherited hormone resistance syndromes. In: McDermott MT, ed. Endocrine secrets. Philadelphia: Hanley and Belfus, 1994 (in press).

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McDermott MT. Interesting endocrine facts and figures. In: McDermott MT, ed. Endocrine secrets. Philadelphia: Hanley and Belfus, 1994 (in press).

McDermott MT. Longitudinal assessment of bone loss in levothyroxine suppressed benign thyroid disease and thyroid cancer. Submitted, Am J Med, 1994. C

GASTROENTEROLOGY SERVICE

INVITED LECTURESHIP:

McNally PR. Endoscopic Ultrasound: An introduction, uses Today and in the future. American College of Gastroenterology Post Graduate Course. January 22,23, 1994

PUBLISHED ARTICLES:

Freeman SR and McNally PR. Diverticulitis. In, Medical Clinics of North America. 1993;5:1149-1167.

Jahns F, Reddy V, Sherman KE. Ascites secondary to renal cell carcinoma: Diagnosis by laparoscopy. J Clin Gastro. (In Press)

Kepczyk T, Kadakia SC, Parker A, Pinkston T. Effect of intravenous erythromycin on gastric emptying. Gastrointest Endosc. 1993;39:469-70.

Lawrence SP and McNally PR. The use of intravenous erythromycin to remove obstructing clot. Gastrointest Endosc. 1994;41:.

Lawrence SP, Larsen BR, Stacy CC, McNally PR. Echoendosonographic and histologic correlation of a fibrovascular polyp of the esophagus. Gastrointest Endosc. 1994;40:81-84.

McNally PR, Rison D, DeAngalis S, Sudduth RH. Colonoscopic polypectomy using the Bi-Bx: Description of a new technique. Gastrointest Endosc. 1994;40:489-91. C

Meier JH, McNally PR, Freeman SR, Stocker N, Punja M, Spaulding HS. Does omeprazole (prilosec) improve asthma in patients with gastroesophageal reflux: A double blind crossover study. Dig Dis Sci. 1994;39: C

Sherman KE, Narkewicz M, Pinto PC. Cyclosporin-A in the treatment of corticosteroid resistent type 1 autoimmune hepatitis. Seminars in Liver Disease.

Sherman KE, O'Brien J, Gutierrez T, Urdea M, Wilber J. Quantitative evaluation of hepatitis C viral RNA in patients with and without concurrent HIV infection. J Clin Micro. 1993;10 (In press) C

PEER REVIEW ARTICLES (in review):

Dewey SM, Davis DD, McNally PR. Solitary rectal ulcer complicated by massive gastrointestinal hemorrhage: Endoscopic diagnosis and management. Gastrointest Endoscopy. In Review

Davis D, Jahns F, Meier J, Freeman S, McNally PR. Pseudomembranous esophagitis: A report of a case and review of the literature. Gastrointest Endosc (Submitted)

Goodman ZD, McNally PR, Davis DR, Ishak KG. "Autoimmune Cholangitis" - a variant of primary biliary cirrhosis. (In submission).

Jahns F and McNally P. Christopher's Syndrome: An unusual cause of shortness of breath in a patient with dysphagia lusoria. J Clin Gastro (Submitted)

Jahns F, Lawrence S, Bute B, McNally P. Appendicitis complicated by abscess and sigmoid fistulae: Endoscopic diagnosis and management. Gastrointest Endosc. In review

Lawrence SP, Yavorski R, Borosky B, Rak K, McDermott M, Merenich J, McNally PR. Correlation between liver density by magnetic resonance imaging and hepatic iron by liver biopsy in the diagnosis of genetic hemochromatosis. In submission.

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Root S, Sudduth RH, Larsen B, McNally PR. Diagnosis and management of cholangiocarcinoma in a patient with recurrent oriental cholangitis. In Submission.

Smith MA, McNally PR, Kadakia SC, Maydonovitch CL, Wong RKH. Esophageal mucosal zinc levels significantly decrease following healing of esophagitis. (In preparation)

Sudduth RH, DeAngalis S, Sherman K, McNally PR. The effectiveness of simethicone in improving visibility during colonoscopy when given with a sodium phosphate solution: a double blind randomized study. Gastrointest Endosc. In Review **C**

Wrench M, Merenich J, Davis D, Lieberman M, McNally PR. Prevalence of gluten sensitive enteropathy in patients with insulin dependent diabetes mellitus. (In Preparation) **C**

NON-PEER REVIEW PUBLICATIONS:

McNally PR. ASGE Guidelines: Patient monitoring during gastrointestinal endoscopic procedures, endoscopic surveillance of upper gastrointestinal malignancy, management of foreign bodies, endoscopic ultrasound. Syllabus Material. Am College Gastroenterology Regional Course Snow Mass, Colorado January 1994.

PUBLISHED CHAPTERS:

Freeman SR and McNally PR. Diverticulitis. In, Medical Clinics of North America. 1993;5:1149-1167.

Smith MT and Lehman GA. Endoscopic management of benign biliary strictures (In Press)

BOOKS:

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PUBLISHED ABSTRACTS:

Lawrence SP, Yavorski R, Borosky B, Rak K, McDermott M, Merenich J, McNally PR. Correlation between liver density by magnetic resonance imaging and hepatic iron by liver biopsy in the diagnosis of genetic hemochromatosis. Hepatology 1994 submitted.

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HEMATOLOGY/ONCOLOGY SERVICE

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ABSTRACTS

Johnson MJ: Chronic toxicities in testicular cancer survivors. Johnson M.J., Vogelzag N.J., Weiss R.B. Pending submission for publication.

Tell D, Rensch M Case report of chronic neutrophilic leukemia-implications for the differential diagnosis of chronic myelogenous leukemia. Proc ACP Tenth Annual Military ACP Meeting, 1993.

Tenglin R: Hematologic abnormalities. In Lillegard W and Rucker K. Handbook of Sports Medicine, Stoneham, MA Butterworth-Heinemann 1993.

INFECTIOUS DISEASE SERVICE

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ABSTRACTS

Artenstein AW, Kim JH, Williams WJ, Chung RCY. Scrofula in adults: Current clinical and diagnostic issues. (Submitted)

Mapou RL, Law WA, Temoshok LR, Wagner K, Malone JL, Skillman DR. Neuropsychological effects of interferon Alfa-N3 in asymptomatic HIV disease, International Neuropsychological Society, Twenty-Second Annual meeting, Cincinnati, OH. Feb, 1994.

Williams WJ, Radulovic S, Dasch GA, Lindstrom J, Kelly DJ, Oster CN, Walker DH. Identification of rickettsia conorii infection by polymerase chain reaction in a soldier returning from Somalia. Clin Infect Dis. 1994;19:93-9.

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Erickson AR, Enzenauer RJ, Nordstrom DM, Merenich JA: The prevalence of hypothyroidism in gout. Submitted, Am J Med, 1994. **C**

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Chang JJ, Yeun JY, Hasbargen JA. Pneumoperitoneum in peritoneal dialysis patients. Peritoneal Dialysis International. 14 (Supplement 1):S57, 1994 (Abstract).

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Culclasure TF, Bray V, Hasbargen JA: Significance of hematuria in the anticoagulated patient: A prospective controlled study. Archives of Internal Medicine 154:649-652, 1994. C

Gillum DM, Yanover MJ, Kuruvila KC, Dillingham MA, Hasbargen JA, McIntyre DO, Anger MS, Harrison MN, Fish EM, Erickson AL, Miller PD: Bone mineral density in stable renal transplant patients. Annual Meeting of the North American Society for Dialysis and Transplantation, August 1994 (Abstract)

Hasbargen JA, Culclasure T: Special Forces medical sergeants (13 Delta) recertification. Military Medicine 159(1):7-9, 1994.

Quinn MJ, Hasbargen JA, Hasbargen BJ: When does peritonitis occur? Peritoneal Dialysis International 14(2):172-174, 1994.

Yeun JY, Hasbargen JA. Comparison of the effect of 16 and 17 gauge needles on bleeding from hemodialysis access sites after needle removal. Journal of the American Society of Nephrology. 4:395A, 1993 (Abstract).

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Yeun JY, et al: Pneumoperitoneum in peritoneal dialysis patients. Submitted Am J Kidney Dis, 1994.

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O'Connell MA, Pluss JL, Schlade P, Henry AR. Goodman AL. Wood Trimmer's Disease in a tractor driver, submitted for publication 1994.

Turner JF, Enzenauer RJ: Bronchiolitis obliterans and organizing pneumonia associated with ankylosing spondylitis. Submitted, Am J Med, 1994.

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Sherman KE, et al: Thymosin Alpha-1 and circulating T-cell subsets in patients with chronic hepatitis C virus infection. Hepatology, Vol 18, #4, 1993. **C**

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Burgess DB, Householder JA, Spicer CL, Smith LR: Positive predictive value and scoring criteria for the Denver II. Submitted, Am Acad Peds, 1994.

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Smith, SL: Three Variables. Letter to editor, Military Medicine, Vol 158, Dec 93.

Smith SL: Sharing the Tools of Primary Care. 2165 words, 23 references, 2 figures, awaits final editorial approval, Military Medicine #93174.

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Rosse RB, Schwartz BL, Kim SY, Deutsch SI: Correlation between antisaccade and Wisconsin card sorting test performance in schizophrenia. Am J of Psychiatry, 150:333-335, 1993.

Spiegel TA, Kaplan JN, Alavi A, Kin SY, Tse KM: Effects of soup preloads on gastric emptying and fullness ratings following an egg sandwich meal. Physiology & Behavior, 56:571-575, 1994.

BOOK CHAPTERS

Blue P, McBiles M: Genitourinary system scintigraphy. Fundamentals of Diagnostic Radiology, Brant WE and Helms CA (eds), Chapter 53, 1208-1219, 1994.

McBiles M, Morita J: Radionuclide imaging of the kidney, urinary tract, and adrenals. Radiology of the Kidney and Urinary Tract, 2nd Edition, Davidson AJ and Hartman DS (eds), Chapter 2, 33-51, 1994.

McBiles M: Correlative imaging of the kidney. Seminars in Nuclear Medicine, XXIV, No 3 (July):219-233, 1994.

DEPARTMENT OF SURGERY

Cho JM, Clark JR, Schofield MJ, Hammond SL, Kolb JR, Homas DW, Mallory PL II: Response of serum cytokines in patients undergoing laparoscopic cholecystectomy **(abstract)** Surgical Endoscopy, p 23, March, 1994. **C**

Cho JM, LaPorta AJ, Clark JR, Schofield MJ, Hammond SL, Mallory PL II: Response of serum cytokines in patients undergoing laparoscopic cholecystectomy. Surgical Endoscopy (accepted for publication). **C**

Yoshida GY: Xanthogranuloma of the external auditory canal. Submitted, Otolaryngology/Head and Neck Surgery, 1994.

ORTHOPEDIC SERVICE

Burkhalter W: Healing after open reduction and internal fixation with exposed metal. Submitted, J Ortho Trauma, 1994.

Callahan BC, et al: Effect of coumadin on fixation of hydroxyapatite-coated and uncoated porous CO-CR-MO alloy implants in a goat model. Orthopaedic Transactions 17(4): poster exhibit (A6), 1994, **(abstract)** J Bone Joint Surgery, In press. **C**

Callahan BC, et al: Alcohol-induced low back pain: Presenting complaint for Hodgkin's Disease. A Case Report and Review of the Literature. J Bone Joint Surg 76A(1):119-121, 1994.

Callahan BC, et al: Hemivertebrae excision for congenital scoliosis. Orthopaedic Transactions. In press. **Abstract**

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Callahan BC, et al: Attachment of hydroxyapatite-coated and uncoated porous implants is influenced by warfarin sodium. Submitted, J Bone and Joint Surg, 1994. **C**

Castello PH, et al: Quantification of lumbar root decompression produced by hemilaminotomy and foraminotomy versus diskectomy using somatosensory-evoked potentials. Orthopaedic Transactions. In press. **Abstract C**

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Hrutkay J, et al: Orthopedic surgery at a mash deployed to Yugoslavia in support of the United Nations Protective Force. Orthopaedic Transactions, **(abstract)** In press. Submitted to Military Medicine 1994.

Hrutkay J, et al: Arthroscopic surgery at a mash in Support of the United Nations. Arthroscopy, In press.

Jones DEC, et al: Efficacy of percutaneous release of the trigger finger: An anatomic study. Orthopaedic Transactions, In Press. **C**

Jones DEC, et al: Carpal ligamentous injuries associated with fractures of the distal radius. Submitted Orthopaedic Transactions, 1994. **C**

Jones DEC, et al: Postoperative joint infections in rheumatoid arthritis patients on methotrexate therapy. Orthopaedics, In press.

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Lisecki EJ, et al: A Clinical comparison of a hydroxyapatite coated VS porous coated total hip implant for use in arthritic human hips (LSF Implant Device). (1) Orthopaedic Transactions, **(abstract)** 17(4):poster exhibit (C1), 1994. (2) Orthopaedic Transactions (from Southern Ortho Asso, Aug 93) In press. (3) Orthopaedic Transactions (from AAOS 94) In press. **C**

Lisecki EJ, et al: Hip lesions mimicking primary osteoarthritis, A radiographic and histopathologic study. Orthopaedic Transactions, **(abstract)** In press.

Lisecki EJ, et al: Injuries and deaths from collecting war souvenirs in Operation Desert Storm. Military Medicine 158(8):505, 1993.

Lisecki EJ,et al: The integrity total hip dystem. Integrity primary anatomic hip. Surgical technique monograph. Monograph with Kirschner Medical Corporation.

Lisecki EJ, et al: Factors influencing bone ingrowth. Orthopaedic Transactions, **(abstract)**, In press. **C**

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replacements by a single surgeon. Submitted, Orthopaedic Transactions, 1994. **C**

McBride JT, et al: The effect of furosemide on swelling in the acutely sprained ankle. Submitted to Am J Sports Med.

Pals S, et al: Patellar tendon healing and strength following patellar tendon autograft harvest in goats. Orthopedic Transactions, (**abstract**) In press. **C**

Place HM, et al: Stabilization of thoracic spine fractures resulting in complete paralysis: A long-term retrospective analysis. Spine 19:1726-1730, 1994.

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Reister JA, et al: The incidence and association of carpal ligamentous injuries with distal radius fractures. Orthopedic Transactions, (**abstract**) In press.

Reister JA, et al: Hip orthoses in children: Upcoming edition of Atlas of Orthotics, Published by Am Acad Ortho Surgeons, In press.

Wroblewski K, et al: Mycobacterium marinum osteomyelitis in an infant with severe combined immunodeficiency. Submitted to orthopaedic Review, 1994.

PRESENTATIONS - FY 94

C - Protocol Related

OFFICE OF THE DEPUTY COMMANDER

Do black females with breast cancer present at a more advanced stage then caucasian females? 16th Annual San Antonio Breast Cancer Symposium, November 5-6, 1993, San Antonio, Texas.

Internal medicine retention study. 10th Army Regional Meeting of the American College of Physicians. November 17-20, 1993, Orlando, Florida.

Racial-differences in breast cancer. 10th Army Regional Meeting of the American College of Physicians. November 17-20, 1993, Orlando, Florida.

DEPARTMENT OF MEDICINE

Gates R, et al: Linking resident educations and quality improvement with preventive medicine - An unlikely marriage. Presented: Association of Program Directors in Internal Medicine, October 1993.

Hanley JF, et al: Limited functional assessment in a pre-operative consult. Presented: American Geriatric Society Annual Meeting, Los Angeles, Ca, 1994.

Hsue G, et al: Treatment of stage II East African trypanosomiasis with melarsoprol. Presented: American College of Physicians, Denver, CO, 1994. **C**

ALLERGY/IMMUNOLOGY SERVICE

Battafarano N: Antispecific immunoglobulin and lymphocytic responses in erythematosus patients following immunizations with three clinically relevant vaccines. Presented: **C**
(1) American College of Rheumatology, November 1993.
(2) Harold S. Nelson 94th Annual Meeting of Military Allergists, 1994.

Battafarano N: Systemic lupus. Presented:
(1) American College of Rheumatology, November 1993.
(2) Harold S. Nelson 94th Annual Meeting of Military Allergists, 1994.

Dubravec V, Dyer PD, Schkade PA. Peripheral eosinophilia from shiitake mushroom in a cholesterol lowering study.

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Ellingson AR, Lieberman M, Muehlbauer S, Lima J, Hoyt A, Battafarano N. Lymphocyte function in a patient with hyper IgM. Association of Military Allergists February 94. **C**

Ellingson AR, Ledoux RS, Weber RW. The Prevalence of dermatophagoides mite allergens in colorado homes utilizing central evaporative coolers. AAAI March 1994. Association of Military Allergists February 1994. **C**

Friesen CD, O'Connell MA, Dyer PD, Schkade PA. Latex induced asthma in a dental assistant case report. Association of Military Allergists February 94.

Kumar SA, Lester MR, Bratton DL. KID (keratosis, ichthyosis, deafness) syndrome associated with elevated sweat chloride. Association of Military Allergists February 94.

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O'Connell MA, Christopher LK, Ranlett RD, Craig DB. Stevens-Johnson syndrome associated with disseminated varicella infection. Association of Military Allergists February 94. American College of Asthma and Immunology, November 1993.

Rodriguez R, Dyer PD, Weber RW, Ledoux BS. Circadian periodicity of tree pollens in Denver, Colorado. Association of Military Allergists, February 1994.

Rodriguez R, Dyer PD. Reactivity to booster pneumococcal vaccine. Association of Military Allergists February 94.

Schkade PA, Routes JM. Hypersensitivity pneumonitis in a patient with hypogammaglobulinemia. AAAI March 94, Aspen Allergy Conference July 1994.

DERMATOLOGY SERVICE

Bennion SD: The effects of toxic epidermal necrolysis and erythema multiforme major patient's sera on human keratinocyte viability in culture. Society of Investigative Dermatology, Carmel, California, February, 1994. **C**

Bennion S: An overview of dermatology and nuclear biologic warfare infections. Eighteenth Annual Uniform Services Dermatology Seminar, Bethesda, Maryland, 5 May 1994.

David-Bajar K: Rheumatology update. American Academy of Dermatology, 52nd Annual Meeting, Washington, D.C., 8 December 1993.

Fitzpatrick JE: Cutaneous lymphomas. Practical Skin Pathology Course, New York, New York, 18 October 1993.

Fitzpatrick JE: Psoriasiform dermatitis. Practical Skin Pathology Course, New York, New York, 19 October 1993.

Fitzpatrick JE: Vasculitis. Practical Skin Pathology Course, New York, New York, 19 October 1993.

Fitzpatrick JE: Disorders of keratinization. Practical Skin Pathology Course, New York, New York, 18 October 1993.

Fitzpatrick JE: Self assessment in dermatopathology. American Society of Dermatopathology Thirty-first Annual Meeting, Washington. D.C., 2 December, 1993.

Fitzpatrick JE: Clinicopathologic Conference. Eighteenth Annual Uniform Services Dermatology Seminar, Bethesda, Maryland, 4 May 1994.

Fitzpatrick JE:: Superficial fungal infections in the battlefield environment. Eighteenth Annual Uniform Services Dermatology Seminar, Bethesda, Maryland, 5 May 1994.

Fitzpatrick JE: Dermatopathology self-assessment workshop. Summer session, American Academy of Dermatology, San Francisco, California, 2 August 1994.

Fitzpatrick JE: Disorders of keratinization. Ninth Combined Skin Pathology Course and Fifth Annual Workshop in Dermatopathology. La Jolla, California, 17 September 1994.

Fitzpatrick JE: Psoriasiform dermatitis. Ninth Combined Skin Pathology Course and Fifth Annual Workshop in Dermatopathology. La Jolla, California, 17 September 1994.

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Gentry RH: Bacterial infections. Eighteenth Annual Uniform Services Dermatology Seminar, Bethesda, Maryland, 5 May 1994.

Gerondale B: Cold-induced vasculitis associated with cryofibrinogenemia, cold urticaria, and renal insufficiency. American Academy of Dermatology, 52nd Annual Meeting, Washington, D.C., 4 December 1993.

Richey T: Cutaneous larva migrans of two years duration due to Brazilian Ancylostoma. American Academy of Dermatology, 52nd Annual Meeting, Washington, D.C., 8 December 1993.

ENDOCRINOLOGY SERVICE

Alex NH, LeMar HJ, McDermott MT: The effect of recombinant growth hormone in patients with severe chronic obstructive pulmonary disease. 76th Meeting of the Endocrine Society, Anaheim, CA. Endocrinology 134 (suppl):283 (329A), 1994. **C**

Christensen RS, Asp AA: Effect of thioamide pretreatment on radioiodine therapy of Graves' Disease. 76th Meeting of the Endocrine Society, Anaheim, CA. 1994.

Georgitis WJ: Retrospective comparison of the efficacy of lovastatin and provastatin. 10th Annual ACP Army Regional Meeting, Orlando, FL. 18 November 1993.

Georgitis WJ: Retrospective comparison of the efficacy of lovastatin and provastatin. 76th Meeting of the Endocrine Society, Anaheim, CA. 1994.

Georgitis WJ: Clinical comparison of lovastatin and provastatin lipid lowering efficacy. Presented: Endocrine Society, Anaheim, Ca, 1994.

GASTROENTEROLOGY SERVICE

Lewey S, DeAngalis S, Bond J, McNally PR. Randomized comparative trial evaluating efficacy of monopolar -vs- bipolar polypectomy snares: Am Coll Physicians, Reston, Va. 26-29 Oct 1994. **C**

Goodman ZD, McNally PR, Davis DR, Ishak KG. "Autoimmune Cholangitis" - a variant of primary biliary cirrhosis. AASLD, Chicago, Illinois, 1993.

Hammond S, DeAngalis S, Rison D, Sudduth R, McNally PR. Colonoscopic polypectomy using the Bi-Bx: Description of a new technique. Am Coll Physicians, Reston, Va. 26-29 Oct 1994. **C**

Lawrence SP, Yavorski R, Borosky B, Rak K, McDermott M, Merenich J, McNally PR. Correlation between liver density by magnetic resonance imaging and hepatic iron by liver biopsy in the diagnosis of genetic hemochromatosis. Am Assoc of Liver Disease. Chicago, Illinois, 11-15 Nov 1994.

Smith MA, McNally PR, Kadakia SC, Maydonovitch CL, Wong RKH. Esophageal mucosal zinc levels significantly decrease following healing of esophagitis. William Beaumont Gastrointestinal

Symposium, Regional ACP Meeting, Buena Vista Palace, Orlando, Fl, 18-21 Nov 1993.

Smith MA, McNally PR, Kadakia SC, Maydonovitch CL, Wong RKH. Esophageal mucosal zinc levels significantly decrease following healing of esophagitis. Dig Dis Week, Boston Mass May 15-21, 1993.

Wrench M, Merenich J, Davis D, Lieberman M, McNally PR. Prevalence of gluten sensitive enteropathy in patients with insulin dependent diabetes mellitus. Am Coll Physicians, Reston, Va. 26-29 Oct 1994. **C**

INFECTIOUS DISEASE SERVICE

Mapou RL, Law WA, Temoshok LR, Wagner K, Malone JL, Skillman DR: Neuropsychological effects of interferon Alfa-N3 in asymptomatic HIV disease. Presented: International Neuropsychological Society, Twenty-Second Annual Meeting, Cincinnati, OH, Feb 1994.

Skillman, DR: Interferon alfa: Anti-HIV activity and clinical use in HIV infection. Grand Rounds: FAMC, 11 Aug 1994.

Williams, WJ: Primary prophylaxis against common infections in HIV-infected patients. 5th Biennial HIV/AIDS Symposium; Specialty Course. Falls Church, VA. 14 Jun 94.

NEPHROLOGY SERVICE

Chang JJ, Yeun JY, Hasbargen JA. Pneumoperitoneum in peritoneal dialysis patients. Poster Presentation at The XlVth Annual Conference on Peritoneal Dialysis, January 1994.

Yeun JY, Hasbargen JA, Slife HF. Renal hypouricemia: Incidence in a United States population and prevention of exercise induced acute renal failure. Poster Presentation at American Society of Nephrology 26th Annual Meeting, November 14-17, 1993.

RHEUMATOLOGY SERVICE

Erickson A. The prevalence of hypothyroidism in gout. Presented at the American College of Physicians National Meeting, April 1994, Miami, Florida.

May KP, Mercill D, West SG, McDermott MT. The effect of methotrexate on mouse osteoblasts. Presented at the 57th Annual National American College of Rheumatology Scientific Meeting, 7-11 Nov 1993, San Antonio, Texas. **C**

DEPARTMENT OF CLINICAL INVESTIGATION

Barrett V, et al: Small ruminant postoperative recovery and restraint device. Presented: Am Vet Med Assoc, San Francisco, Ca, 1994. **C**

Harris R, et al: Impact of rapid group A strep optimal immunoassay test on antibiotic usage in pediatric clinics. Presented: American Society of Microbiology, Las Vegas, NV, 1994. **C**

Sherman KE, et al: Combination therapy with thymosin alpha-1 and interferon alfa in the treatment of hepatitis C. Presented: 4th International Symposium on Combination Therapies, June 1994. **C**

PHARMACY SERVICE

Conyers Dr. Implementing pharmaceutical care in the internal medicine clinic. Presented: ASHP Midyear Conference, Atlanta, Ga, Dec 93.

Craghead Col: Implementation of pharmaceutical care. Presented: Eisenhower AMC Regional Army Pharmacy Conference, Augusta, Ga, Oct 93.

Craghead Col: Providing pharmaceutical care in the ambulatory environment - from concept to practice. Presented: 1994 University of Wisconsin Federal Pharmacy Program, Sep 94.

Hicks Maj. Implementation of pharmaceutical care at FAMC. Presented: Tri-Service Pharmacy Seminar, San Antonio, Tx, Mar 94.

DEPARTMENT OF PSYCHIATRY

Frank PR: Care of the suicidal adolescent. Presented: University of Health Sciences College of Osteopathic Medicine's Annual Review Course in Clinical Medicine for the General Physician, Kansas City, MO, September 1994.

Kolb MM: Adult survivors of child abuse. Presented: Association of Military Osteopathic Physicians & Surgeons Annual Convention, April, 1994.

Kolb MM: Evaluation of the psychotic patient. Presented: Association of Military Osteopathic Physicians & Surgeons Annual Convention, April, 1994.

Westfried E: Developmental shifts or adaptations?: A study of group therapy with young older adults. Presented: 47th Annual Scientific Meeting of the Gerontological Society of America, 1994. **C**

DEPARTMENT OF PEDIATRICS

Burgess D: Screening for lead poisoning. Presented: Western Society of Pediatric Research, Carmel, CA, 1994. **C**

Carter B: Hypertrophic cardiomyopathy and disproportionate septal in newborns. Presented: Western Society for Pediatric Research, Carmel, CA, 1994.

PREVENTIVE MEDICINE SERVICE

Jackson C: Health promotion in the primary care setting. OTSG Health Promotion Conference, Baltimore, MD, June 1994.

DEPARTMENT OF PRIMARY CARE AND COMMUNITY MEDICINE

Smith SL: Uncertainty. Patient Education Conference poster, AAFP/STFM, Phoenix, AZ, with Rob Hamm, PhD, University of Oklahoma HSC, 18-21 Nov 93. This poster presently under consideration by Department of Preventive Medicine and Biometrics for display 27 Oct 94 in 13th Annual Epidemiologic Research Exchange, Dennis Lezott, PhD, Program Chair.

Smith SL: Understanding uncertainty. Poster accepted for 17-20 Nov 94 Patient Education Conference, Orlando, FL, sponsor AAFP/STFM with Rob Hamm, PhD, University of Oklahoma HSC.

PHYSICAL MEDICINE AND REHABILITATION SERVICE

Muscari CT: The dorsal scapular nerve: A study of normals. AAEM Forty-First Annual Scientific Meeting, 29 September 1994, San Francisco, CA.

DEPARTMENT OF RADIOLOGY

NUCLEAR MEDICINE SERVICE

Renal nuclear medicine section of board review course, Annual Meeting of Society of Nuclear Medicine, Orlando, FL, Jun 1994.

Imaging necrotic myocardium. Army Nuclear Medicine Technology Review Course '93, Fitzsimons Army Medical Center, Aurora, CO, 10 Aug 93.

Monoclonal antibody imaging. Army Nuclear Medicine Technology Review Course '93, Fitzsimons Army Medical Center, Aurora, CO, 13 Aug 93.

Cardiovascular imaging. Internal Medicine Service, Fitzsimons Army Medical Center, Aurora, CO, 15 Oct 93.

Nuclear cardiology. Nuclear Pharmacy Course, University of Colorado School of Pharmacy, Denver, CO, 30 Nov 93.

Radioimmunoscintigraphy. Rocky Mountain Chapter of Nuclear Medicine Technologists, Jewish Hospital, Denver, CO, 30 Nov 93.

Gamma cameras. Nuclear Pharmacy Orientation Course '94, Fitzsimons Army Medical Center, Aurora, CO, 15 Feb 94.

Lung scintigraphy. Nuclear Pharmacy Orientation Course 94, Fitzsimons Army Medical Center, Aurora, CO, 15 Feb 94.

Functional brain imaging. Nuclear Pharmacy Orientation Course '94, Fitzsimons Army Medical Center, Aurora, CO, 16 Feb 94.

DEPARTMENT OF SURGERY

Cho JM, LaPorta AJ, Clark JR, Schofield MJ, Hammond SL, Mallory PL II: Response of serum cytokines in patients undergoing laparoscopic cholecystectomy. Society of Gastrointestinal Surgeons, Nashville, Tennessee, April 18, 1994. **C**

Cho JM, LaPorta AJ, Clark JR, Schofield MJ, Hammond SL, Mallory PL II, et. al.: Biochemical and cytokine evidence or early intervention in the timing of laparoscopic cholecystectomy following ERCP and sphincterotomy (Poster). The American College of Surgeons 80th Annual Clinical Congress, Chicago, Illinois, October 9-14, 1994. **C**

LaPorta AJ, LaFave M, Hutton J, Mallory PL II: High velocity impact water trauma: Unique experience of the golden gate bridge. The American College of Surgeons, Colorado Chapter, Colorado Springs, Colorado, May 13, 1994.

Morrison CA, LaPorta AJ, Mallory PL II: Biliary tract obstruction and the afferent loop syndrome. Gary P. Wratten Surgical Symposium, Cloudcroft, New Mexico, April 19-23, 1994.

Williams DL: Verification of permissible ambient noise levels allowed in an audiometric test room for hearing conservation and audiometry. Presented: Military Audiology Short Course, Richmond, VA, April 1994. **C**

NEUROSURGERY SERVICE

Ecklund J, Swengel R, Ellenbogen R: Cortical Mapping - Techniques and current options. Presented at Neurosurgery in the Rockies. Vail, Colorado; March 1994.

Ecklund J: Spinal cord trauma - Pathophysiology and treatment rationale. Presented at Military Spine Study Group. Augusta, Georgia; August 1994

ORTHOPEDIC SERVICE

Callahan BC, et al: Hemivertebrae excision for congenital scoliosis. Presented:
(1) Barnard Competition (Denver, CO, Mar, 1993). Winner.
(2) American Academy of Orthopaedic Surgeons (New Orleans, 24 Feb - 01 Mar 94). POSTER.
(3) AOA Residents Conference (Atlanta, GA, Mar 94).

Callahan BC, et al: Latex Allergy: A Threat to you and your patient. Presented:
(1) American Academy of Orthopaedic Surgeons (New Orleans, 24 Feb - 01 Mar 94). POSTER.
(2) AOA Residents Conf (Atlanta, GA, Mar 94).
(3) Barnard Competition (Denver, CO, Mar 94).

Castello PH, et al: Quantification of lumbar root decompression produced by hemilaminotomy and foraminotomy versus diskectomy using somatosensory-evoked potentials. Presented:
(1) Academy of Surgical Research (Breckenridge, CO, 30 Sep - 02 Oct 93).
(2) American Academy of Orthopaedic Surgeons (New Orleans, LA, 24- 28 Feb 94). Scientific Exhibit.
(3) Society of Military Orthopaedic Surgeons (Bethesda, MD,12-17 Dec 93).
(4) Barnard Competition (Denver, CO, Mar 94).
(5) Mid-Central States, Orthopaedic Society, Inc.(Steamboat Springs,CO, 16-19 Jun 94)
(6) 12th Annual Orthopedic Residents' Conference, Memphis, TN, August 1994. **C**

Castello PH, et al: Multifocal avascular neurosis in scleroderma. Presented: Mid Central States, Orthopaedic Society, Inc. (Steamboat Springs, CO, 16-19 Jun 94).

Castello PH, et al: A comparison of patellar graft fixation techniques in anterior cruciate ligament (ACL) reconstruction using a goat model. Presented:
(1) Rocky Mountain Chapter, Wester Orthopedic Association, Snowmass, CO, July 1994.
(2) 12th Annual Orthopaedic Residents' Conference, Memphis, TN, August 1994. **C**

Chang L, et al: Silicon drain tube breakage and retention. Presented:
(1) Academy of Surgical Research (Breckenridge, CO, 30 Sep - 03 Oct 93).

(2) Society of Military Orthopaedic Surgeons (Bethesda, MD 12-17 Dec 93) POSTER.

Chang L, et al: Forearm rotation in upper extremity casts. Presented: Barnard, Denver, CO 1994. **C**

Chang L, et al: Comparison of short-arm casts VS intermediate-length casts VS long-arm casts for quantity of arm motion. Presented: Barnard Competition (Denver, CO, Mar 94). **C**

Clyde ME, et al: Healing of segmental bone defects in goat tibia. Presented:
(1) Academy Of Surgical Research (Breckenridge, Co, 30 Sep - 01 Oct 93). POSTER.
(2) Barnard Competition (Denver, CO, Mar 94). **C**

Clyde ME, et al: Use of autologous bone marrow and allograft bone powder in the treatment of nonunions: A preliminary report. Presented: Society of Military Orthopedic Surgeons (Bethesda, MD, Nov 93). POSTER. **C**

Clyde M, et al: Comparison of three pneumatic compression devices for the prevention of deep Vein thrombosis after joint replacement surgery. Presented: Western Orthopedic Association, Snowmass, CO, July 1994. **C**

Cope EE, et al: Effect of proximal cerclage cable on proximal hip prosthesis micromotion: A cadaveric study. Presented: Academy of Surgical Research (Breckenridge, CO, 30 Sep - 02 Oct 93). **C**

Farber G, et al: Analysis of instrumented spine fusion with emphasis on complications and use of radiographs for pedicle screw placement. Presented: Society of Military Orthopaedic Surgeons (Bethesda, MD, 12-17 Dec 93).

Farber G, et al: Disc herniation in cervical spine fractures. Presented:
(1) Barnard Competition (Denver, CO, Mar 94).
(2) Rocky Mountain Chapter, Western Orthopaedic Association (29-31 Jul 94, Snowmass, CO).
(3) Scoliosis Research Society (Portland, OR, 21-24 Sep 94).

Farber G, et al: Legg-Calve-Perthes disease: Treatment using abduction casts. Presented: 1993 Children's Orthopaedic Day (The Children's Hospital, Denver, CO, 1993).

Farber G, et al: Accuracy of pedicle screw placement in lumbar fusions by plain radiographs and computed tomography. Presented: CICDs XIth International Congress, Bordeaux, France, 1994. **C**

Friedel SP, et al: Comparison of three postoperative autologous transfusion devices in 300 total hip and total knee joint recipients. Presented:
(1) Academy of Surgical Research (Breckenridge, CO, Oct 93).
(2) Barnard Competition (Denver, CO, Mar 94). WINNER.
(3) Rocky Mountain Chapter, Western Orthopaedic Association (Denver, CO, Apr 94).
(4) Hugh Mahon Research Competition (Denver, CO, Apr 94). WINNER. **C**

Friedel SP, et al: Acute spinal injuries in winter sports. Presented:
(1) Colorado Spine Symposium, 4th Annual Meeting (Denver, CO, 5 Nov 93).
(2) Society of Military Orthopaedic Surgeons (Washington, DC, Dec 93). POSTER.

Grant M, et al: Retrospective comparison of osteolysis and loosening in porous ingrowth and cemented tibial components of total knee prosthesis. Presented: Barnard Competition (Denver, CO, Mar 94).

Grant M, et al: Radiographic evaluation of osteolysis in the tibial component in total knee arthroplasty. Presented: Barnard Competition, Denver, CO, March 1994.

Hrutkay J, et al: Orthopedic surgery at a mash deployed to Yugoslavia in support of the United Nations protective force. Presented: Society of Military Orthopaedic Surgeons (Washington DC, Dec 93).

Jones DEC, et al: Efficacy of percutaneous release of the trigger finger: An anatomic study. Presented:
(1) Academy of Surgical Research (Breckenridge, CO, 30 Sept - 01 Oct 93).
(2) Society of Military Orthopaedic Surgeons (Washington DC, 12-17 Dec 93).
(3) American Society for Surgery of the Hand, 49th Annual Meeting, Cincinnati, Ohio, October 1994. **C**

Jones DEC, et al: Carpal ligamentous injuries associated with fractures of the distal radius. Presented: Annual Meeting of the Association of Bone & Joint Surgeon, Carlsbad, Ca, 1994. **C**

Kim et al: The effect of furosemide on swelling in the acutely sprained ankle. Presented: Barnard Competition. (Denver, CO, Mar 94).

Lisecki EJ, et al: A clinical comparison of a hydroxyapatite coated VS porous coated total hip implant for use in arthritic human hips (LSF Implant Device). Presented:

(1) Society of Military Orthopaedic Surgeons (Bethesda, MD, 12-17 Dec 93).
(2) American Academy of Orthopaedic Surgeons (New Orleans, LA, 24 Feb - 01 Mar 94).
(3) Reconstructive Surgery of Hip and Knee Course (Steamboat Springs, CO, 22-29 Jan 94). **C**

Lisecki EJ, et al: Hip lesions mimicking primary osteoarthritis, a radiographic and histopathologic study. Presented: American Academy of Orthopaedic Surgeons (New Orleans, LA, 24-28 Feb 94).

Lisecki EJ, et al: Nicotine administration in goats: methodological considerations. Presented: Academy of Surgical Research (Breckenridge, CO, 30 Sep - 01 Oct 93). **C**

Lisecki EJ, et al: Osteolysis. Presented:
(1) Advances in Total Joint Arthroplasty Symposium (Park City, Utah, 19-22 Jan 94).
(2) Reconstructive Surgery of the Hip and Knee Course (Steamboat Springs, CO, 22-29 Jan 94).

Lisecki EJ, et al: Noncemented anatomic total hip arthroplasty. Presented: 3rd Annual Hip, Knee, and Shoulder Joint Replacement Symposium (Aspen, CO, 24-26 Mar 94).

Lisecki EJ, et al: Three-year followup Results with the hydroxyapatite coated and uncoated porous longterm stable fixation in the total hip system. Presented: 3rd Annual Hip, Knee and Shoulder Joint Replacement Symposium, March, 1994. **C**

Lisecki EJ, et al: Factors influencing bone ingrowth. Presented: Southern Orthopaedic Association (Southampton, Bermuda, 19-21 Aug 94). **C**

McBride JT, et al: Comparison of three sizes of interference screws for graft fixation of the central one-third of the patellar tendon in anterior cruciate ligament reconstruction in a cadaveric goat model. Presented: Academy of Surgical Research (Breckenridge, CO, 30 Sep - 01 Oct 93). **C**

McBride JT, et al: Evaluation of endoscopic interference screws for fixation of the central one-third patellar tendon in anterior cruciate reconstruction in a goat model. Presented:
(1) Rocky Mountain Chapter, Western Orthopaedic Association (Snowmass, CO, 29-31 July 94). **C**
(2) 12th Annual Orthopaedic Residents' Conference, Smith & Nephew Richards (Memphis, TN, 26-27 Aug 94).

McBride JT, et al: The effect of furosemide on swelling in the acutely sprained ankle. Presented:
(1) Barnard Competition, Denver, CO, March 1994.

(2) 12th Annual Orthopaedic Residents' Conference, Memphis, TN, August 1994.
(3) Western Orthopedic Association, Snowmass, CO, July 1994. **C**

Nelson B, et al: The use of mitek suture anchors in the repair of ulnar collateral ligament injuries of the thumb: A clinical and biomechanical Study. Presented: Barnard Competition. (Denver, CO, Mar 94).

Pals S, et al: Patellar tendon healing and strength following patellar tendon autograft harvest in goats. Presented: Academy of Surgical Research (Breckenridge, CO, 30 Sep - 01 Oct 93). **C**

Petersen B, et al: Use of Electrical Stimulation for Treatment of Stress Fractures. Presented: Barnard Competition (Denver, CO, Mar 94).

Petersen B, et al: Pulsed electromagnetic fields as therapy for treatment of tibial and metatarsal stress fractures. Presented: 12th Annual Orthopaedic Residents' Conference, Memphis, TN, August 1994. **C**

Place HM, et al: Stabilization of thoracic spine fractures resulting in complete paralysis: A long-term retrospective analysis. Presented:
(1) Rocky Mountain Chapter, Western Orthopaedic Association (Snowmass,CO, 29 Jul - 01 Aug 93).
(2) Society of Military Orthopaedic Surgeons (Washington DC, 12-17 Dec 93).

Reister JA, et al: The incidence and association of carpal ligamentous injuries with distal radius fractures. **C**
Presented:
(1) Rocky Mountain Chapter, Western Orthopaedic Association (Snowmass, Co, 29 Jul - 01 Aug 93).
(2) American Academy of Orthopaedic Surgeons (New Orleans, LA, 24 Feb - 01 Mar 94).
(3) Barnard Competition (Denver, CO, Mar 94). WINNER.
(4) Hugh Mahon Research Competition (Denver, CO, Apr 94). SEMI-FINALIST.

Reister JA, et al: Cervical discogenic pain: A correlation of magnetic resonance imaging and discography/CT discograms. Presented: American Academy of Orthopaedic Surgeons (New Orleans, LA, Feb 94).

Wolff JD, et al: Effects of methotrexate of hydroxyapatite-coated and uncoated porous CO-CR-MO alloy implants in a goat. Presented: Academy of Surgical Research (Breckenridge, CO, 29 Sep - 01 Oct 93). **C**

Table of Contents for Detail Summary Sheets
by Department, FAMC Protocol Number, and Protocol Title

Legend	Protocol Totals	
O=ongoing	O	231
C=completed	C	54
T=terminated	T	103
P=publication		
PR=presentation	Total	388

DEPARTMENT OF MEDICINE

91/102 SWOG 8894 A Comparison of Bilateral Orchiectomy with or without Flutamide for the Treatment of Patients with Histologically Confirmed Stage D_2 Prostate Cancer

91/104 SWOG 8925 Evaluation of Cisplatin + VP-16 Followed by Mitotane at Progression if no Prior Mitotane OR Cisplatin + VP-16 Only if Prior Treatment with Mitotane in Advanced and Metastatic Adrenal Cortical Carcinoma

91/118 SWOG 9013 A Prospective Randomized Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus: Chemotherapy Plus Surgery versus Surgery Alone for Patients with Local Regional Disease, Phase III

91/119 SWOG 9039 Evaluation of Quality of Life in Patients with Stage D-2 Cancer of the Prostate Enrolled in SWOG 8894

91/133 SWOG 9111 (EST 1690) Post-Operative Adjuvant Interferon Alpha 2 in Resected High-Risk Primary and Regionally Metastatic Melanoma, Intergroup

91/150 SWOG 9007 Cytogenetic Studies in Leukemia Patients, Ancillary

91/151 SWOG 9108 A Phase III Comparison of Fludarabine Phosphate vs Chlorambucil vs Fludarabine Phosphate Plus Chlorambucil in Previously Untreated B-Cell Chronic Lymphocytic Leukemia

92/101 SWOG 8913 Evaluation of Mebarone in Malignant Melanoma, Phase II

92/102 SWOG 8956 A Phase II Study of Cisplatin and 5-FU Infusion for Treatment of Advanced and/or Recurrent Metastatic Carcinoma of the Urinary Bladder

92/122 SWOG 9061 A Phase III Study of Conventional Adjuvant Chemotherapy versus High Dose Chemotherapy and Autologous Bone Marrow Transplantation as Adjuvant Intensification Therapy Following Conventional Adjuvant Chemotherapy in Patients with Stage II and III Breast Cancer at High Risk of Recurrence

92/143 SWOG 9035 - Randomized Trial of Adjuvant Immunotherapy with an Allogeneic Melanoma Vaccine for Patients with Intermediate Thickness, Node Negative Malignant Melanoma (T3NOMO) Phase III

93/107 SWOG 9030 Phase II Study of High Dose Ara-C/Mitoxantrone for the Treatment of Relapsed/Refractory Acute Lymphocytic Leukemia

90/150 SWOG 8905 Phase II/III Study of Fluorouracil (F-FU) and Its Modulation in Advanced Colorectal Cancer

90/154 SWOG 8326 Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blastic Crisis, Phase III

90/155 SWOG 8810 Six Courses of 5-Fluorouracil and Cisplatinum with Correlation of Clinical and Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinoma of the Head and Neck, Phase II Pilot Study

90/160 SWOG 8897 Phase III Comparison of Adjuvant Chemotherapy with or without Endocrine Therapy in High-Risk, Node Negative Breast Cancer Patients and a Natural History Followup Study in Low-Risk, Node Negative Patients

90/175 SWOG 8931 Phase III Comparison of Cyclophosphamide, Doxorubicin and 5-Fluorouracil (CAF) and a 16-Week Multi-drug Regimen as Adjuvant Therapy for Patients with Hormone Receptor Negative, Node-Positive Breast Cancer

91/103 SWOG 8906 Evaluation of Merbarone in Hepatoma, Phase II

91/109 SWOG 9037 Prediction of Recurrence and Survival in Node-Negative Breast Cancer Patients Using a Panel of Prognostic Factors. A Companion Protocol to SWOG 8897

91/139 SWOG 9045 Evaluation of Quality of Life in Patients with Advanced Colorectal Cancer Enrolled on SWOG 8905

91/148 SWOG 8911 Evaluation of Piroxantrone in Refractory Carcinoma of the Breast, Phase II

91/149 SWOG 8936 Evaluation of Piroxantrone in Gastric Cancer

93/110 SWOG 9215 Quality of Life on Breast Cancer Adjuvant Trail (SWOG 8931)

93/118 SWOG 9134 A Phase II Trial of Taxol and Granulocyte-Colony Stimulating Factor (G-CSF) in Patients with Advanced Soft-Tissue Sarcoma

DEPARTMENT OF SURGERY

Gynecology Service

90/351 O GOG 109 A Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy VS Radiation Therapy Alone in Selected Patients with Stage 1A-2, 1B or 2A Carcinoma of the Cervix Following Radical Hysterectomy and Node Dissection

91/350 O GOG 26II A Phase II Trial of 5-FU and High Dose Leucovorin in Patients with Advanced/Recurrent Pelvic Malignancies

91/352 O GOG 102H A Phase II Study of the Intraperitoneal Administration of Recombinant Interleukin-2 in Residual Ovarian Carcinoma

91/353 O GOG 109 A Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy vs Radiation Therapy Alone in Selected Patients with Stage 1A-2, 1B or 2A Carcinoma of the Cervix Following Radical Hysterectomy and Node Dissection

91/357 O GOG 26LL A Phase II Trial of Prolonged Oral Etoposide (VP-16) in Patients with Advanced Pelvic Malignancies

92/351 O GOG 119: A Study of the Use of Provera and Tamoxifen Citrate (NSC #180973) for the Treatment of Advanced, Recurrent or Metastatic Endometrial Carcinoma

93/351 O GOG 114 A Phase III Randomized Study of Intravenous Cisplatin and Cyclophosphamide Versus Intravenous Cisplatin and Taxol Versus High Dose Intravenous Carboplatin Followed by Intravenous Taxol and Intraperitoneal Cisplatin in Patients with Optimal Stage III Epithelial Ovarian Carcinoma

93/352 O GOG 120 A Randomized Comparison of Hydroxyurea Versus 5-FU, Hydroxyurea Infusion and Bolus Cisplatin Versus Weekly Cisplatin as Adjunct to Radiation Therapy in Patients with Stages II-B, III, IV-A Carcinoma of the Cervix and Negative Para-Aortic Nodes, Phase III

93/353 O GOG 132 A Phase III Randomized Study of Cisplatin (NSC #119875) Versus Taxol (NSC #125973) Versus Taxol and Cisplatin in Patients with Suboptimal Stage III and IV Epithelial Ovarian Carcinoma

93/354 O GOG 134 A Phase III of Taxol at Three Dose Levels and G-CSF at Two Dose Levels in Platinum-Resistant Ovarian Carcinoma

DEPARTMENT OF PEDIATRICS

92/404 T POG 9152 IRS-IV Stage 4 and/or Clinical Group IV Disease

92/406 T POG 9031 Treatment of Children with High-Stage Medullobastoma: Cisplatin/VP-16 Pre- vs Post-Irradiation: A Phase III Study

92/407 T POG 9135 Pre-Radiation Chemotherapy for Children with Supratnetorial Malignant Gliomas and Poorly-Differentiated Embryonal Tumors. A Randomized Phase II Study

92/408 T POG 9136 Phase I/II Dose Escalating Trial of Hyperfractionated Irradiation in the Treatment of Supratentorial Malignant Tumors of Childhood

92/412 T POG 9132 Hyperfractionated Irradiation for Posterior Fossa Ependymoma. A Phase II/III Study

92/414 T POG 9259 Carboplatin in the Treatment of Newly-Diagnosed Metastatic Osteosarcoma or Unresectable Osteosarcoma: A POG Phase III Study

92/420 T POG 9233/34 A Phase III Randomized Trial of Standard vs Dose-Intensified Chemotherapy for Children 3 Years of Age with a CNS Malignancy Treated with or without Radiation Therapy

92/421 T POG 9243 Treatment for Children with Intermediate-Risk Neuroblastoma: POG Stage B (All Ages) and Stages C, D, And DS (365 Days at Diagnosis)

93/401 T POG 9226 Treatment of Stage I, IIa and IIIa, Hodgkin's Disease with ABVE and Low-Dose Irradiation

93/404 T POG 9047 Neuroblastoma Biology Protocol

93/405 T POG 9048 Treatment of Children with Localized Malignant Germ Cell Tumors-A Phase II Study

93/406 T POG 9049 High Risk Germ Cell Protocol

93/407 T POG 9130 Treatmentof Newly Diagnosed Low-Grade Astrocytoma. A Phase III POG/CCSG Intergroup Study

93/408 T POG 9239 Cisplatin and Hyperfractionated vs Conventional Radiotherapy for Brain Stem Glioma

93/409 T POG 9227 Treatment of Recurrent or Refractory Hodgkin's Disease with Cyclosporine-A, Actinomycin-D, Vincristine. A Phase II Study

DEPARTMENT OF PRIMARY CARE & COMMUNITY MEDICINE

DEPARTMENT OF NURSING

PHYSICAL MEDICINE SERVICE

DEPARTMENT OF PREVENTIVE MEDICINE

ENVIRONMENTAL HYGIENE ACTIVITY-WEST

MEDDAC

COLORADO DEPARTMENT OF HEALTH

Detail Summary Sheet

(1) Date: 5 Apr 94 (2) Protocol #: 80/120 (3) Status: Terminated

(4) Title: Evaluation of Carbohydrate Metabolism in Thyrotoxicosis: Investigations into the Frequency, Type and Mechanisms of Carbohydrate Tolerance

(5) Start Date: 1981 (6) Est Compl Date: 1993

(7) Principal Investigator: Gerald S. Kidd, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology (10) Associate Investigators:

(11) Key Words: carbohydrate hyperthyroidism

Fred D. Hofeldt, COL,(Ret)
Robert J. Sjoberg, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 11
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The first objective of the study is to determine the frequency and reversibility of carbohydrate intolerance in thyrotoxicosis and to determine the importance of gut factors by doing oral and intravenous glucose tolerance test. The second objective is to study the mechanisms of carbohydrate intolerance. This objective will be approached by measuring glucose, insulin, glucagon and free fatty acids, basally and after oral intravenous glucose and by measuring the responses to exogenous insulin.

(16) Technical Approach: Ten non-diabetic patients who are taking no medications, are less than age 45, are less than 120% of ideal body weight, will be studied while thyrotoxic and after recovery. Eachpatient will have an oral and an intravenous glucose tolerance test. Each patient will have an insulin tolerance test basally and following glucose infusion.

(17) Progress: No progress in several years. All investigators PCS.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 81/117 (3) Status: Ongoing

(4) Title: The Role of Calcitonin in Osteoporosis

(5) Start Date: Reactivate 1987 (6) Est Compl Date:

(7) Principal Investigator: Michael T. McDermott, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:

(11) Key Words:
osteoporosis
bone density
calcitonin deficiency
thyroid hormone

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 243
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if, longitudinally, thyroid cancer patients who have calcitonin deficiency and are on suppressive doses of thyroid hormone, loose radial bone more rapidly than goiter patients, who are also on suppressive doses of thyroid hormone but are not calcitonin deficient, and than normal controls. Also to compare these 3 groups, cross-sectionally, for bone density of the spine and hip.

(16) Technical Approach: 3 Groups: (a) thyroid cancer patients - calcitonin deficient and on thyroid hormone; (b) goiter patients - not calcitonin deficient but are on thyroid hormone, and (b) normal controls. (SPA) single photon absorptiometry-distal and midradius serially for 5-6 yrs (in progress since 1981) (DPA) dual photon absorptiometry - spinal & hip- cross-sectionally.

(17) Progress: Data collection is complete. Longitudinal bone mass changes have been calculated as the slope of the lines depicting adjusted bone mass values over time. Consistent with our original hypotheses bone loss was fastest in the cancer group which also had the highest synthyroid doses of T4 levels. Bone loss was next fastest in the goiter group and slowest in the controls. These differences were all statistically significant at the spine, hip and forearm. Analysis of ancillary demographic data is in progress and a manuscript is in preparation.

FY94: Analysis of ancillary demographic data is complete, and the manuscript was submitted for publication.

Publications:

McDermott MT, Kidd GS, Blue P, Ghaed V, Hofeldt FD: Reduced bone mineral content in totally thyroidectomized patients: Possible effect of calcitonin deficiency. J Clin Endocrinol Metab 56:936-9, 1983.

McDermott MT, Hofeldt F, Kidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. J Bone Min Res (1(suppl. 1):352, 1986 (Abstract).

Presentations:

McDermott MT, Hofeldt FD, Kidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. Presented: 8th Annual Scientific Meeting, American Society for Bone and Mineral Research, Anaheim, CA 1986.

Perloff JJ, McDermott MT, Damiano MA, Kidd GS: The effects of thyroid hormone suppression and calcitonin deficiency on bone mass. 74th meeting of the Endocrine Society, San Antonio, TX, June 1992.

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 81/118 (3) Status: Ongoing

(4) Title: Hypothalamic Pituitary Gonadal Function in Hypothyroidism

(5) Start Date: 1981 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Michael T. McDermott, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:
Gerald S. Kidd, COL, MC

(11) Key Words:
hypothyroidism
gonadal dysgenesis
gonadotropins, pituitary

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The objectives of this protocol are to define more clearly the mechanisms of gonadal dysfunction occurring in hypothyroidism and to see if these abnormalties resolve after treatment of the hypothyroid state.

(16) Technical Approach: A prospective study to assess in a pair manner results of alterations in HPG axis as a consequence of hypothyroidism when evaluated with GnRH infusion and TRH testing, clinical stimulation and HCG testing in males and females.

(17) Progress: No progress in the past two years.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 83/126 (3) Status: Ongoing

(4) Title: The Role of Altered Prostaglandin Synthesis in the Impaired Water Excretion and Abnormal Renin-Aldosterone Axis of Hypothyroidism

(5) Start Date: 1983 (6) Est Compl Date:

(7) Principal Investigator: Michael McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/ Endocrine (10) Associate Investigators: Gerald Kidd, COL, MC

(11) Key Words:
prostaglandin synthetic
hypothyroidism

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to determine in an indirect manner i.e., with prostaglandin synthesis inhibition, if the abnormal suppressibility of vasopressin and/or altered renal sensitivity to vasopressin seen in hypothyroid patients is caused by altered prostaglandin levels. This will be done by measuring serum vasopressin levels and urinary water excretion in response to a water load, as well as the renal response to exogenous vasopressin, in hypothyroid patients with and without prostaglandin synthesis inhibition, both before and after treatment with thyroid hormone to the point of euthyroidism. In the same way, the influence of altered prostaglandin levels on the renin-aldosterone axis of hypothyroidism will be studied by measuring plasma renin activity and aldosterone levels in these patients while in a relatively volume depleted state, that is before the water loading is performed. Altered renal prostaglandin synthesis in hypothyroidism will also be assessed directly by measuring urinary PGE-2 excretion in the hypothyroid and euthyroid states. (Urinary PGE-2 excretion is thought to reflect primarily renal PGE-2 production.)

(16) Technical Approach: By measuring urinary prostaglandin E and water loading responses in hypothyroid patients before and after indomethacin

administration as well as measuring plasma, aldosterone, and plasma renin activity we will evaluate the effects of prostaglandin synthesis inhibition on water metabolism.

(17) Progress: Because of funding problems, we are asking the University of Colorado to measure ADH levels, and as soon as they agree, the study will begin. No progress in FY94,

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Apr 94 (2) Protocol #: 84/119 (3) Status: Terminated

(4) Title: Treatment of Graves' Ophthalmopathy with Cyclosporin

(5) Start Date: 1984 (6) Est Compl Date:

(7) Principal Investigator:
Michael T. McDermott, LTC, MC
Leonard Wartofsky, COL, MC

(8) Facility: FAMC
WRAMC
MAMC
BAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
Anthony Truxal, CPT, MC

(11) Key Words:
eye disease
cyclosporin
prednisone

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". Cyclosporinte - Acne (1 pt.) Prednisone - Acne, swelling (1 pt.) Arthralgia on withdrawal (1 pt.)

(15) Study Objective: To determine the effectiveness of cyclosporin in the treatment of Graves' eye disease.

(16) Technical Approach: Patients with Graves' eye disease will receive a 3-week course of cyclosporine or prednisone, then have a 3-week rest. Then, 3 weeks of prednisone or cyclosporine (crossover). They will be followed by complete eye examination and CT scan of the orbits before and after each drug period, and twice weekly with CBC, SMA-18, urinalysis and B-2 microglobulin (urine).

(17) Progress: No new patients enlisted from FAMC in the past year. FY92-93 - no progress.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 1 Mar 94 (2) Protocol #: 85/167 (3) Status: Terminated

(4) Title: The Effect of Age on Thyroid Function Studies: The Perchlorate Discharge Test

(5) Start Date: 1985 (6) Est Compl Date: 1992

(7) Principal Investigator: William Georgitis, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators

(11) Key Words:
thyroid diseases
thyroid function tests
thyroid gland

Gerald Kidd, COL, MC
Michael T. McDermott, MAJ, MC
Peter Blue, LTC, MC
Stephen M. Manier, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine the effect of age on the perchlorate discharge test in individuals with thyroid disease.

(16) Technical Approach: Patients over the age of 60 years without thyroid disease by history, physical examination and lab evaluation will be studied. A perchlorate test will be performed in Nuclear Medicine.

(17) Progress: No progress has been made with this protocol. For the following reasons recommend termination of the protocol: 1) Lack of control group to establish valid normal limits to the test. 2) This test is rarely used anymore for clinical purposes and, therefore, ability to publish results is in question. 3) Methods in nuclear medicine including equipment to measure uptakes are changing, raising questions about the validity of comparing the data from 12 patients studied previously to any control group assembled about a decade later.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 86/114 (3) Status: Ongoing

(4) Title: Natural History of HIV 1 Infection and Disease in a United States Military Community

(5) Start Date: 1986 (6) Est Compl Date: Ongoing

(7) Principal Investigator: Wheaton Williams, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators Richard Harris, LTC, MS Jefferey Casserly, PA-C

(11) Key Words: HIV virus

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 37
d. Total Number of Subjects Enrolled to Date: 670
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To develop an accurate, thorough understanding of the pattern of disease progression and clinical course in individuals with documented HIV infection within the general military population including active duty, dependents, and retirees. This will provide critical information for clinical and administrative management of patients.

(16) Technical Approach: Collect data on all patients who are required to be staged by DA directives and any who request staging.

(17) Progress: Continuing to enroll newly diagnosed HIV patients.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Oct 94 (2) Protocol #: 88/115 (3) Status: Ongoing

(4) Title: The Impact of an Ambulatory Care Rotation on Interns Psychosocial Attitudes

(5) Start Date: 1989 (6) Est Compl Date: 1998

(7) Principal Investigator: Michael J. Weaver, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Int. Med. Svc. (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 50-60
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: We propose to test the hypotheses that this ambulatory care rotation will result in increased awareness of psychosocial problems and the increase in awareness will be correlate with an increase in knowledge of psychosocial content.

(16) Technical Approach: Each intern who does a one month ambulatory care rotation in the internal medicine clinic is given a cognitive knowledge test and a psychosocial attitudes questionnaire at the beginning of the rotation, and again at the end of the rotation.

(17) Progress: Two years of questionnaires have been administered to interns who are now junior and senior residents. Protocol was amended in May 92 to extend the study up to 6 years, administering the same questionnaire to these residents to determine the long-term changes in attitude through training and into their first years of practice or subspecialty training. FY94: Average 8 interns per year enrolled in this study.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 2 Aug 94 (2) Protocol #: 88/121 (3) Status: Ongoing

(4) Title: Bone Densitometry in Thyroid Extract Treated Patients

(5) Start Date: 1988 (6) Est Compl Date: 1995

(7) Principal Investigator: (8) Facility: FAMC
William J. Georgitis, LTC,MC

(9) Dept/Svc: MED/Endocrine Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:Approved
c. Number of Subjects Enrolled During Reporting Period:30 controls
d. Total Number of Subjects Enrolled to Date: 50
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether thyroid extract has greater adverse effects on bone density and calcium metabolism than synthetic l-thyroxine. The second is to assess the reversibility of any documented effect.

(16) Technical Approach: The effects of thyroid extract treatment on bone densitometry will be investigated. Subjects taking thyroid extract treatment matched with a thyroxine controlled group will have assessments of thyroid replacement therapy status, mineral metabolism and bone density. Thyroid extract subjects found to be subclinially hyperthyroid may enter a longitudinal assessment of bone density after crossing over to euthyroid thyroxine replacement.

(17) Progress: FY94: Subclinically hyperthyroid patients changed from thyroid extract to 1-thyroxine continue to have annual BMD determinations (n=7).

Publications and Presentations:

1. Georgitis WJ, Abrams LF, Dolbow A, Bunker DM: Bone densitometry in patients taking thyroid extract. Presented: American Society for Boen and Mineral Research/International Conference on Calcium-regulating Hormones. 1st Joint Meeting. Abstract 219:S172, Montreal, Quebec, September 1989.

2. Abrams L, Georgitis W, Dolbow A, Bunker D, Kidd G: Is anyone taking thyroid extract consistently euthyroid? The Endocrine Society, 72nd Meeting, Atlanta, GA, 1990.

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 89/102 (3) Status: Ongoing

(4) Title: Factors Determining Peak Bone Mass and Subsequent Bone Loss

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Michael T. McDermott, LTC, MC

(9) Dept/Svc: MED/Endocrinology (10) Associate Investigators:

(11) Key Words:
bone density
peak bone mass

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine factors associated with the development of peak bone mass and subsequent bone loss.

(16) Technical Approach: Bone density of the radius (single photon absorptiometry) and of the hip and spine (dual photon absorptiometry) will be done in a large group of male and female volunteers, who will also, on another protocol, be having total body fat and lean mass measured by dual photo absorptiometry. Questionnaire concerning present and past calcium intake, exercise and other habits will also be administered.

(17) Progress: No progress to date.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 89/104 (3) Status: Terminated

(4) Title: Efficacy of Corticosteroids in the Acute Treatment of Asthma: Is Duration of Symptoms Important?

(5) Start Date: Sep 89 (6) Est Compl Date: Sep 91

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy (10) Associate Investigators: David L. Goodman, LTC, MC

(11) Key Words:
asthma
corticosteroids
emergency management

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if the beneficial effect of corticosteroids seen in the treatment of status asthmatics is dependent on the duration of asthmatic symptoms.

(16) Technical Approach: 120 subjects presenting to the E.R. or allergy clinic with acute episode of asthma will be studied. Subjects will receive either 125mg methylpredisolone or placebo within 30 minutes of arriving for tx. They will be divided into 2 sps - these with IRS of <24 hours duration and those with sxs for more than 24°. Spirometry and admission rate will be analyzed.

(17) Progress: PI PCS'd.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 89/105 (3) Status: Ongoing

(4) Title: Appropriate Blood Pressure Control in Diabetes Trial Protocol (ABCD Trial)

(5) Start Date: 1991 (6) Est Compl Date: 1998

(7) Principal Investigator: Michael McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:

(11) Key Words:
nephropathy
diabetes

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 10
d. Total Number of Subjects Enrolled to Date: 52
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" **To date no serious adverse events by FAMC patients thought to be secondary to study involvement.**

((15) Study Objective: a)Define a level of blood pressure control in a prospective, randomized, non-blinded fashion needed to prevent or delay the progression of diabetic nephropathy and other microvascular complications of diabetes; b) determine if there is a specific advantage to either a CEI or a Ca++ channel blocker as a mode of treatment for hypertension in regard to the onset or progression of diabetic nephropathy.

(16) Technical Approach: See protocol.

(17) Progress: Approximately 52 Fitzsimons Army Medical Center patients have been enrolled in the protocol without complications. Apparently city-wide approximately 800 patients have agreed to participate, and several hundred are actively involved.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 89/108 (3) Status: Ongoing

(4) Title: Efficacy of Pentoxifylline in Treating Diabetic Impotence

(5) Start Date: 1989 (6) Est Compl Date:

(7) Principal Investigator: William Georgitis, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:

(11) Key Words:
diabetes
impotence
pentoxifylline

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 60
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if pentoxifylline is more effective than placebo in improving sexual function in non-insulin dependent diabetic men.

(16) Technical Approach: A single center, double-blind, placebo controlled study to examine the efficacy of pentoxifylline in improving sexual function in impotent NIDDM men. Diabetic men with impotence who meet the protocol entrance criteria will be randomly assigned placebo or pentoxifylline for 12 weeks. After completion of the treatment course subjects will be reevaluated, and groups will be compared to determine beneficial effects.

(17) Progress: Data collection phase complete. All volunteers have finished medication as of 1 Oct 92. We are now in data synthesis phase. FY94: A manuscript is in the preparation phase, and an abstract was presented at a national meeting.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 5 Oct 93 (2) Protocol #: 90/100 (3) Status: Ongoing

(4) Title: Platelet Thromboxane and Aggregation and Whole Blood Prostacyclin Synthesis in Human Thyroid Disease

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Nadine Alex, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrinology (10) Associate Investigators: Michael T. McDermott, LTC, MC Sharon Noble, DAC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Oct b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 22
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the roles of thromboxane and prostacyclin in mediating the phenomenon associated with thyroid dysfunction.

(16) Technical Approach: See protocol.

(17) Progress: As of this date pre- and post- data have been completed on 22 patients. Need about 38 more patients to complete the study. No complications. Laboratory methods are analysis are progressing well. New investigators have been added to the study. No progress since FY93 report.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 Aug 94 (2) Protocol #: 90/102 (3) Status: Completed

(4) Title: Effect of Prolonged Administration of Iodine Containing Water Purification Tablets in Man

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Michael T. McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrinology (10) Associate Investigators: William J. Georgitis, LTC, MC Homer LeMar, MAJ, MC

(11) Key Words: iodine goiter thyroid

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if prolonged iodine administration (3 mos) causes persistent hypothyroidism or if compensation occurs and if goiters occur.

(16) Technical Approach: Iodine containing water purification tablets (4 tabs/day, 8mg iodine/tab) will be given to 15 subjects for 3 months. Baseline studies will include thyroid hormone and TSH levels, a TRH test, a radioactive iodine uptake and thyroid ultrasound thereafter, thyroid hormone levels, tSH and TRH test will be repeated at 7, 28 and 90 days. The radioactive iodine uptake will be separated at 7 and 90 days and the thyroid ultrasound will be repeated at 90 days.

(17) Progress: Eight volunteers have completed the entire study. All data has been collected. Complete statistical analysis shows that during prolonged administration of water purification tablets thyroid hormone levels remain persistently decreased, TSH is persistently increased, the radioiodine uptake is promptly and persistently suppressed and thyroid gland size progressively increases.

CONTINUATION SHEET FY 94 ANNUAL PROGRESS REPORT Protocol No. 90/102

Presentations:

Georgitis WJ, Lemar HJ, McDermott MT: Goitrogenic effect of tetraglycine hydroperiodide water purification tablets. Presented: Am. College of Physicians (Army Regional Meeting) San Francisco, Ca, November 1992.

Hughes G, Lemar H, Georgitis W, McDermott M, Asp A, Merenich J, Kidd GS: Suppression of thyroid radioiodine uptake by tetraglycine hydropeniodide water purification tablets. Presented: Am. College of Physicians (Army Regional Meeting), San Francisco, Ca, November 1992.

Publications:

Lemar HJ, Georgitis WJ, McDermott MT: Thyroid adaptation to chronic tetraglycine hydroperiodide water purification tablet use. J Clin Endocrinol Metab (in press 1994).

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 90/103 (3) Status: Terminated

(4) Title: The Limulus Amoebocyte Lysate Assay for the Diagnosis of Spontaneous Bacterial Peritonitis in Ascitic Fluid

(5) Start Date: 1990 (6) Est Compl Date: June 1991

(7) Principal Investigator: Kenneth E. Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Gastro. (10) Associate Investigators: Spencer Root, MD

(11) Key Words:
limulus
SBP

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 13
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: Determine efficacy of the limulus amoebocyte lysate assay in the early diagnosis of Gram negative spontaneous bacterial peritonitis.

(16) Technical Approach: The limulus assay is run on peritoneal fluid obtained from patients with ascites, and then compared to standard cell count/culture definitions of SBP.

(17) Progress: Lab studies encouraging. Patient population inadequate to evaluate efficacy.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 1 Mar 94 (2) Protocol #: 90/112 (3) Status: Ongoing

(4) Title: Laboratory Screening to Detect Biochemical Evidence of Hemochromatosis Among Patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM)

(5) Start Date: 1990 (6) Est Compl Date: 1994

(7) Principal Investigator: Michael McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrine (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 240
d. Total Number of Subjects Enrolled to Date: 800
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a systemic means for all NIDDM patients at FAMC to be screened and to make physicians aware of the need for this intervention.

(16) Technical Approach: See protocol.

(17) Progress: Finished data collection, expect paper to be written in Fall 1994.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 May 94 (2) Protocol #: 90/114 (3) Status: Completed

(4) Title: Assessment of Patient Utilities for Health Outcomes: Influence on Aspirin Prophylaxis to Prevent Myocardial Infarction

(5) Start Date: 1990 (6) Est Compl Date: 1994

(7) Principal Investigator: Michael J. Weaver, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Gen. Int. Med. (10) Associate Investigators: Peter Laird, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 72
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: To determine what patients' utilities are for various health outcome states: (1) MI; (2) mild CVA; (3) moderate - severe CVA. Determine whether patient utilities influence decision to take ASA to prevent MI.

(16) Technical Approach: Decision analysis tree constructed using probabilities from published trials of ASA as prophylaxis against MI. Determine patient utilities by standard reference gamble interview.

(17) Progress: The decision analysis has been restructured and is being reanalyzed. FY94: Data collection completed.

Publications and Presentations: One presentation.

Detail Summary Sheet

(1) Date: 5 Apr 94 (2) Protocol #: 90/117 (3) Status: Ongoing

(4) Title: The Effect of Prolonged Thyroxine Suppression Therapy on Thyroid Nodule Size, Cytology and Serum Thyroglobulin in Patients with Solitary Palpable Thyroid Lesions

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Arnold Asp, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrine (10) Associate Investigators: Michael McDermott, COL, MC William Georgitis, COL, MC Mark Larson, LTC, MC

(11) Key Words: thyroid

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 13
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if suppressive doses of levothyroxine (documented by an 'ultrasensitive" TSH assay) reduces the size (by ultrasound) of newly discovered, biopsy "non-malignant" thyroid nodules; if response to suppression therapy differs between patients with truly uninodular lesions VS those in whom ultrasound examination uncovers the presence of multiple nodules; if any FNA cytologic changes occur after a course of suppression therapy and the utility of serum thyroglobulin as a biochemical marker of changes in nodular size or cytology.

(16) Technical Approach: See protocol.

(17) Progress: Began recruiting patients Summer, 1992. Thirteen patients enrolled to date. No complication or problems.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Jun 94 (2) Protocol #: 90/122 (3) Status: Completed

(4) Title: Evaluation of Viral Hepatitis in Patients Infected with the Human Immunodeficiency Virus (HIV)

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Kenneth Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastro. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JUNE b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate the prevalence of serologic markers of viral hepatitis including hepatitis B, hepatitis C, and hepatitis D in a military population and to determine the effect of AZT therapy on the markers of HB infection.

(16) Technical Approach: Bank sera of 220 HIV subjects will be used. Sera banked prior to AZT therapy will be studied using qualitative hepatitis B DNA probe assay. Data will be correlated to helper: suppressor status and serum markers of hepatic injury. Hepatitis C assay by ELISA will be performed on serial serum samples and at 6 months to 1 yr intervals to determine the incidence of hepatitis C in this population. Hepatitis D antibody testing will be performed in all HBsAG positive samples as well as any that may be HBV DNA positive but antigen negative on testing.

(17) Progress: Statistical evaluation and refinement of data in preparation for final publication is underway. Collaborative work with Chiron Corp. has led to the validation of quantitative techniques for hepatitis C in the HIV infected population.

Publications:

Sherman KE, Freeman S, Harrison S, Andron L: Prevalence of Antibody to Hepatitis C Virus in Patients Infected with the Human Immunodeficiency
Virus. J. Inf. Dis, 163:414-415, 1991.

Sherman KE, O'Brien J, Gutierrez A, Morse P, Freeman S, Andron L, Harrison, S. Serologic and Genomic Markers of Viral Hepatitis in Patients with HIV Infection. (Abstract) **Gastroenterology**, (in press).

Sherman KE, O'Brien J, Gutierrez A, Harrison, Urdea M, Neuwald P and Wilber J: Quantitative evaluatin fo the hepatitis C virus RNA in patients with concurrent HIV infection (J. Clin. Micro, Oct, 1993).

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 90/132 (3) Status: Ongoing

(4) Title: Prevention and Treatment of Steroid Induced Osteoporosis

(5) Start Date: 1990 (6) Est Compl Date: 1994

(7) Principal Investigator:
Michael McDermott, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:
John Merenich, MAJ, MC
William Georgitis, LTC, MC
James Singleton, MAJ, MC
Sterling West, LTC, MC
Nadine Alex, CPT, MC

(11) Key Words:
osteoporosis
steroids

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 28
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Prevention and treatment of steroid induced osteoporosis.

(16) Technical Approach: Randomized controlled prospective single blind evaluation of the efficacy of a coherence therapy regimen in the prevention and treatment of steroid induced osteoporosis.

(17) Progress: Patients are being studied with more undergoing enrollment. Five patients have withdrawn for personal reasons.
FY94: Four subjects enrolled this report period for a total of 28. Total of 15 patients have withdrawn for personal health or reassignment/relocation reasons. No drug reactions thus far. This leaves a total of 13 patients ; 4 have completed the study and 11 are ongoing study subjects.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 90/133 (3) Status: Completed

(4) Title: The Effect of Antihistamines on Urination

(5) Start Date: 1990 (6) Est Compl Date: 1994

(7) Principal Investigator:
Shashi Kumar, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc

(10) Associate Investigators:
Ron Sutherland, MAJ, MC
Brant Thrasher, CPT, MC
Paul Schkade, MAJ, MC

(11) Key Words:
antihistamine

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if various antihistamines alter the urinary flow in normal, healthy men or in men with prostatic hypertrophy.

(16) Technical Approach: This is a multi-phase study using various commonly prescribed antihistamines. This is a randomized double blind, placebo-controlled, cross-over design. Thirty subjects will be randomized to receive either chlorpheniramine 8 mg BID or identical appearing placebo BID for 1 week each, with a washout period of 1 week between the two treatment periods.

(17) Progress: In Jan 93 the Addendum 3 was added to the original design of the study. The title was changed from "The Effect of Terfenadine on Urination" to the title as above to reflect the design of the study.

Publications and Presentations: American Academy of Allergy & Immunology, San Francisco, Ca, Presented March 1991. Aspen Allergy Meeting, July 1991, Presented.

Abstract submitted to American Academy of Allergy and Immunology Meeting, Anaheim, CA, April, 1994.

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 90/152 (3) Status: Terminated

(4) Title: Residual Renal Function in Dialysis Patients

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator:
James Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology

(10) Associate Investigators:
Barbara Hasbargen, RN, BSN
E. Fortenbery, MAJ, MC

(11) Key Words:
dialysis
renal function

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The principal objective of the study is to elucidate the relationship between modality of dialysis and residual renal function.

(16) Technical Approach: Fifteen patients who are on hemodialysis and 15 patients who are on CAPD and approximately 6 patients that will change from one modality to the other will be studied using blood samples and renal scans.

(17) Progress: No progress FY 93. FY94: PI ETS.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 91/106 (3) Status: Ongoing

(4) Title: A Randomized, Controlled Trial of Interferon Alpha and Thymosin Alpha-1 in Patients with Hepatitis C Antibody Positive Chronic Active Hepatitis

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator:
Dirk Davis, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Gastroenterology

(10) Associate Investigators:
Spencer Root, MD
Zachary Goodman, MD, PhD
Kamal Ishak, MD, PhD
Kenneth Sherman, MD

(11) Key Words:
hepatitis
interferon alpha
thymosin alpha-1

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 23
d. Total Number of Subjects Enrolled to Date: 52
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Demonstrate efficacy of recombinant interferon alpha 2b among military personnel and those eligible for care under the auspices of DOD for treatment of chronic hepatitis C. Attempt to augment the response to interferon using Thymosin alpha-1 as in a immunomodulator.

(16) Technical Approach: Randomized, three-arm study: 1) treatment with interferon alpha + placebo; 2) interferon alpha + thymosin alpha-1; and 3) placebo (controls). Six-month study cycles with 40 adult chronic hepatitis C patients per arm.

(17) Progress: To date 56 patients with chronic active hepatitis attributable to viral hepatitis C have been enrolled at FAMC. There have been no serious adverse events associated with drug therapy. One patient was dropped due to evidence of non-compliance. One patinet missed several key visits and was dropped. One patient decided to discontiue participation at 12 weeks. WRAMC enrolled fiv additional patients for a total of 9. Preliminary analysis shows evidence of IFA/TA-1 response.

Publications: Sherman KE, et al: Thymosin Alpha-1 and circulating T-cell subsets in patients with chronic hepatitis C virus infection. Hepatology, vol 18, no 4, Oct 93.
Presentations: None

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 91/107 (3) Status: Ongoing

(4) Title: Does Omeprazole (Losec*) Improve Respiratory Function in Asthma Patients with Gastroesophageal Reflux? A Double-Blind, Crossover Study

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Peter McNally, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Gastroenterology (10) Associate Investigators: Michael Fisher, MAJ, MC MC Nancy Stocker, Phar.D.

(11) Key Words:
GI reflux
omeprazole
asthma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Nov b. Review Results:
c. Number of Subjects Enrolled During Reporting Periood: 20
d. Total Number of Subjects Enrolled to Date: 35
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this study is to determine whether asthmatic patients with GER will experience improved respiratory function when GER is treated with omeprazole.

(16) Technical Approach: Patients will be randomized to drug or placebo and evaluated by a number of tests to include gastrointestinal investigation to evaluate for GER, intermittent pulmonary function testing, blood tests, esophageal manometry, Bernstein test, 24=hr. esophageal pH monitoring and EGD.

(17) Progress: To date 35 patients enrolled. Preliminary data: 25% of asthma patients with GERD show objective improvement in PFT's when GERD treated with Omeprazole. FY94: Enrollment continues. Amendment "An Open Label Dose Ranging Extension Study to Evaluate the Efficacy of Omeprazole for 12 Weeks in Asthma Patients with Gastroesophageal Reflux" was added in Mar 94.

Presentations: Preliminary data presented: Dig. Dis. Week, April 1992; Follow-up presented Am. Coll Gastro, October 1992.

Detail Summary Sheet

(1) Date: 7 Dec 93 (2) Protocol #: 91/113 (3) Status: Ongoing

(4) Title: The Effect of Recombinant Growth Hormone on Pulmonary Function in Patients with Chronic Obstructive Pulmonary Disease

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator: Michael McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrinology (10) Associate Investigators:

(11) Key Words:
growth hormone
COPD

Michael McCormack, CPT, MC
Marin Kollef, MAJ, MC
William Georgitis, LTC, MC
John Merenich, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" No adverse reactions

(15) Study Objective: To test the effect of recombinant growth hormone on breathing ability.

(16) Technical Approach: Randomized, prospective, double-blind, placebo-controlled design using recombinant human growth hormone or sterile saline placebo in patients with severe chronic obstructive pulmonary disease currently under follow-up in the Pulmonary Clinic at FAMC. Patients will be treated for one year.

(17) Progress: Fifteen patients were recruited. Six have dropped out for various reasons; inconvenience, intermittment illness and being "tired of taking shots" were the most common reasons. No one dropped out due to side effects. Six have completed one year, have had their final studies and are now off treatment. Three are from 3-7 months into the study and are doing well. Data collected thus far has not been analyzed as we remain blinded as to their treatment until the study's end.
FY94: Eight patients completed the study. Seven dropped out for a variety of reasons, non related to the medications. There was one death but he was found to be in the placebo group. Final data is currently being analyzed.
Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 93 (2) Protocol #: 91/114 (3) Status: Ongoing

(4) Title: Detection of Renal Artery Stenosis by Noninvasive Testing

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator: Jane Yeun, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Nephrology (10) Associate Investigators:

(11) Key Words:
renal artery stenosis
captopril
enalaprilat
renogram

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the specificity and sensitivity of Captopril challenge, Captopril renogram, Enalaprilat renogram, and duplex ultrasonography in the diagnosis of RAS compared to the standard arteriography.

(16) Technical Approach: All patients studies will undergo captopril challenge, captopril renogram, enalaprilat renogram, duplex ultrasonography and renal arteriogram. Power analysis will be conducted to determine requirements for total number of patients after first 20 enrolled.

(17) Progress: No progress this FY. Patient enrollment slower than anticipated. Data collection only to this point.
FY94: No progress since FY93 Annual Progress Report.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 91/122 (3) Status: Ongoing

(4) Title: A Multicenter, Double-Blind Study to Evaluate the Safety and Therapeutic Efficacy of Omeprazole 20mg A.M. or 10mg A.M. as Compated to Placebo During 12/24 Months Maintenance Treatment of Patients with Duodenal Ulcer Healing Following 4 Weeks of Omeprazole 20mg A.M.

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Gastroenterology

(10) Associate Investigators:
John Meier, MAJ, MC
Robert Sudduth, MAJ, MC
Nancy Stocker, Pharm.D.

(11) Key Words:
omeprazole
duodenal ulcer
investigational new drug

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this investigational new drug study is to determine if patients identified to have a duodenal ulcer that is healed with omeprazole can be prevented from experiencing an ulcer relapse when given on of two dosages or concentrations of this medicine when compared to a placebo.

(16) Technical Approach: After endoscopy verifies ulcer healing with omeprazole, patients will be randomized to receive either maintenance treatment with omeprazole (10 mg or 20 mg each morning) or placebo. Laboratory tests and EGD will be performed.

(17) Progress: Twelve patients have been enrolled to date. Eight entered the maintenance phase, two have elected not to participate in the 2nd year of maintenance and one had recurrent PUD in the 2nd year. No signifiant AEs.

FY94: No new subjects enrolled this report period because enrollment is closed. Subjects are completing the maintenance phase. Anticipate completion of the study sometime in Jan 94 with data analysis to follow. Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Feb 94 (2) Protocol #: 91/125 (3) Status: Ongoing

(4) Title: An Ultrastructural Study of the Dermal-Epidermal Junction Following Skin Splitting with Various Methods

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator: Kathleen David-Bajar, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Dermatology (10) Associate Investigators: Scott Bennion, LTC, MC SSG Tom Johnson Ron Jackson

(11) Key Words: skin splitting

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Feb b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate a reproducible site of separation, routine use of such "split skin" methods that will become the standard for the indirect immunofluorescence evaluation of bullous skin disorders.

(16) Technical Approach: Specimens of discarded human adult skin and neonatal foreskin will be subjected to dermal-epidermal separation using each of three methods: NaCl, EDTA, and dispase. Each specimen will then be processed for electron microscopy, after incubation in specific monoclonal antibodies to known anatomic components of the dermal-epidermal junction. Two investigators independently evaluate and be blinded to the source of the specimens in making their assessments.

(17) Progress: For much of the last year we did not have an electromicroscopy technician. A new technician, SSG Johnson is now working on this project and has successfully processed intact neonatal skin. He is learning the split-skin techniques, and will begin working on the immunogold staining as soon as reagents are received.

FY94: Three methods for chemically splitting skin have been tested. Transmission electron microscopy has shown that with 1M NaCl treatment epidermal-dermal splits occur exclusively in the lamina lucida of the basement membrane zone; these results are consistent with expected hypotheses. Work continues on developing immunogold labeling for specific antigen staining of basement membrane components.

Detail Summary Sheet

(1) Date: 1 Feb 94 (2) Protocol #: 91/126 (3) Status: Terminated

(4) Title: Efficacy of Oral Cromolyn Sodium in Documented Adverse Food Reactions, A Double-Blind Placebo-Controlled Trial with Food Challenges

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator: Bryan Martin, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Allergy (10) Associate Investigators: Anthony Henry, LTC, MC T. Ray Vaughan, MAJ, MC

(11) Key Words: food reactions cromolyn sodium

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_ FEB____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____2_____
d. Total Number of Subjects Enrolled to Date:_____10_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the efficacy of oral cromolyn sodium in patients with documented adverse food reactions.

(16) Technical Approach: Food skin testing and breathing tests will be done followed by food challenges, using placebo or real food, to document subject's reaction. Subjects will be randomized to placebo or drug. After 10 days the subjects will be re-challenged in a double-blind fashion. After a two-week washout, subjects will be crossed over and the challenges repeated after 10 days.

(17) Progress: Ten patients screened, 3 entered protocol, 2 completed protocol, no adverse reactions. Having problems finding appropriate subjects. All investigtors have PCS'd.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 4 Jun 94 (2) Protocol #: 91/134 (3) Status: Ongoing

(4) Title: The Use of Cultured Skin Cells and Monoclonal Antibodies to Evaluate the Development and Function of Various Proteins in Keratinocytes and Other Epidermal and Dermal Cells

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator:
Scott Bennion, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Dermatology

(10) Associate Investigators:
James Fitzpatrick, LTC, MC
Loren Golitz, MD, UCHSC
Ron Jackson, PhD

(11) Key Words:
keratinocytes
monoclonal antibodies

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Through the use of cultured human epidermal cells this study will determine the specificity of monoclonal antibodies for certain skin protein antigens implicated in skin tumors and whether the expression of these antigens changes with alterations in the celll culture environment such as density of cells and exposure to UV light.

(16) Technical Approach: This study involves a number of highly technical laboratory procedures as outlined in the protocol.

(17) Progress: Continue to evaluate staining methods to determine the optimal staining procedures for the cultured human keratinocytes (HKs) with vimentin and cytokeratin. In addition we are also planning to alter the calcium concentrations of the cultures to alter the HK differentiation. We feel that the differentiation of the HKs may play an important part in the expression of both cytokeratin and vimentin.
FY94: No progress since FY93 annual progress report.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 1 Feb 94 (2) Protocol #: 91/127 (3) Status: Completed

(4) Title: Effectiveness of Simethicone to Improve Visibility During Colonoscopy When Given with a Peroral FLEET Diphosphate Laxative: A Double-Blind Randomized Placebo Controlled Study

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator: Robert Sudduth, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Gastroenterology (10) Associate Investigators: Nancy Stocker-Stolpman, PharmD Peter McNally, LTC, MC

(11) Key Words: colonoscopy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Feb b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 75
d. Total Number of Subjects Enrolled to Date: 101
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To prospectively determine if the co-administration of simethicone with Fleet per oral bowel pre can improve preparation for colonoscopy.

(16) Technical Approach: The subject population (220) will be randomized to Fleet with simethicone or to Fleet with placebo. During colonoscopy the investigators will use a scoring system to evaluate the number of bubbles and visibility while examining five areas of the colon.

(17) Progress: Going well with 75 patients enrolled and now our goal is 100. Should be done by Summer of 1993. FY94: 101 patients were randomized and the data is being analyzed.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 91/143 (3) Status: Ongoing

(4) Title: A Multi-Center Randomized Comparative Trial Evaluating Safety and Efficacy of Monopolar Versus Bipolar Polypectomy Snares

(5) Start Date: 1991 (6) Est Compl Date: 1995

(7) Principal Investigator: Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Gastroenterology

(10) Associate Investigators:
Thomas Kepczyk, MAJ, MC
Scot Lewey, MAJ, MC
Milton Smith, LTC, MC
Dirk Davis, MAJ, MC
Steve Lawrence, MAJ, MC
James Cremins, MAJ, MC

(11) Key Words:
polypectomy
snares

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 44
d. Total Number of Subjects Enrolled to Date: 294
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To compare the efficacy, generator settings, and complication rates in the use of the monopolar versus bipolar polypectomy snares for the removal of colonic polyps.

(16) Technical Approach: Large sessile and pedunculated polyps will be lassoed with either the wire snare or the Bi-Snare in a standard fashion. For the Bi-Snare, electrical current will be applied using current settings of CUT 7 wats & COAG 6 with BLEND 2 on FORCE 1B; 1.0 CUT & 1.5 COAG blended-cut on the SSEL2. For the monopolar, electrical current will be applied using standard settings of coagulation 3 and cut 0, at 1 to 2 second pulses.

(17) Progress: Study is ongoing. Interim data analysis showed better results with the Bisnare, but have not reached statistical significance yet. Request one additional year for enrollment.

FY94: Bi-Snare appears to be superior (trend, P non significant). Request permission to continue study n=100, and reanalyze data then (approx. 1 yr).

Publications and Presentations: Two presentations.

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 91/136 (3) Status: Ongoing

(4) Title: I. A Clinical and Radiographic Comparison of Parenteral Gold Versus Parenteral Methotrexate in the Treatment of Early Rheumatoid Arthritis. II. The Effect of Low-Dose Methotrexate on Bone Metabolism and Bone Density

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator: Sterling West, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Rheumatology (10) Associate Investigators:

(11) Key Words:
arthritis
methotrexate
bone density

Michael McDermott, LTC, MC
Paul Miller, MD, UCHSC
Daniel Battafarano, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 40
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Part I: a) to compare the clinical efficacy of parenteral gold and parenteral methotrexate in the treatment of rheumatoid arthritis; b) to compare radiographic progression of RA in these two treatment groups. Part II: to evaluate the effect of low-dose methotrexate on bone metabolism and bone density.

(16) Technical Approach: Patients will be randomly assigned to receive either intramuscular methotrexate or gold. Laboratory tests and bone densitometries will be performed periodically to monitor rheumatoid arthritis and drug therapy.

(17) Progress: Patient accrual continues.
FY94: As of 31 May 94 40 subjects were enrolled, enrollment complete. Subjects are now undergoing serial evaluations including DEXAs. This study will be completed by 31 Dec 94.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Oct 93 (2) Protocol #: 92/105 (3) Status: Ongoing

(4) Title: Bi-Bx Removal of "Hard to Reach' Colon Polyps: A Pilot Evaluation of a New Polypectomy Technique

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro

(10) Associate Investigators
Robert Sudduth, MAJ, MC
Sofia DeAngelis, RN

(11) Key Words:
colon polyps
polypectomy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 25
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the utility of a new biopsy technique.

(16) Technical Approach: Prospective evaluation with followup for technical success and complications.

(17) Progress: Twenty-fivee patients enrolled to date, no complications or untoward side effects. Plan to continue patient enrollment. Preliminary description of new technique submitted for publication.

Publications: Am J Gastro 87:1329, 1992
Presentations: Will be presented in FY 93

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 91/146 (3) Status: Terminated

(4) Title: Work of Breathing as a Predictor of Failure to Wean From Mechanical Ventilation in Patients with Severe Chronic Obstructive Pulmonary Disease

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Jack DePriest, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Med/MICU (10) Associate Investigators:

(11) Key Words: COPD

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To prospectively determine whether measuring the work of breathing by metabolic cart in patients with severe COPD can be useful in predicting their ability to sustain spontaneous respirations. It will also validate or determine new cutoff values for the CROP score and f/Vt ratios.

(16) Technical Approach: Just prior to extubation the patient will have his work of breathing measured by the metabolic cart. The patient is then extubated as planned. The patient will then be followed to see if he tolerates extubation or develops respiratory failure, requiring reintubation.

(17) Progress: Three subjects studied, one completed. Due to down-sizing of the Army, budget cuts, elimination of the new Pulmonary Fellowship, and lack of eligible subjects, the study cannot be completed as planned. Study will continue while PI is at FAMC and perhaps in the next two years sufficient subjects may be studied to provide evaluable data or some type of useful information.

FY94: No progress.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 92/109 (3) Status: Ongoing

(4) Title: Characterization of a Human Thyroid Cancer Cell Line

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: (8) Facility: FAMC
William Georgitis, COL, MC

(9) Dept of MED/Endocrine (10) Associate Investigators

Tony Gutierrez

(11) Key Words:
cell line thyroid
thyroid cancer

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Identify and characterize an immortal thyroid cancer cell line in terms of degree of differentiation and thryoid cell/molecular biology.

(16) Technical Approach: The cells will be studied using a variety of techniques including immunohisto chemistry, molecular biology and radioisotope methods.

(17) Progress: Positive immunohistochemical staining for thyroglobulin has been found. Samples of cell culture line have been provided to investigators at other research institutions in the United States.

Presentations:

1. Society of Uniformed Endocrinologists meeting, (poster) June 1992.

2. American Thyroid Association (poster) September 1992.

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 92/107 (3) Status: Ongoing

(4) Title: Treatment of Graves' Disease with Cholestyramine

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Arnold Asp, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Endocrine

(10) Associate Investigators

Michael McDermott, LTC, MC
Gregory B. Hughes, MAJ, MC

(11) Key Words:
hyperthyroidism
cholestyramine

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 6
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". **Three patients have developed constipation while taking cholestyramine.**

(15) Study Objective: To evaluate the efficacy of adding cholestyramine to conventional antithyroid drug therapy in rapidly achieving a euthyroid state in patients with active hyperthyroid graves disease.

(16) Technical Approach: Parallel two-group repeated measures design in hwich half the patients receive traditional therapy with methimazole and ateolpl, while the other half receive methimazole and atenolol plus cholestryramine for a period of four weeks.

(17) Progress: Six patients enrolled at FAMC. Seven patients enrolled at WRAMC.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Dec 93 (2) Protocol #: 92/111 (3) Status: Terminated

(4) Title: The Effect of Exogenous Thyrotropin Releasing Hormone on Plasma Atrial Natriuretic Peptide

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Michael McDermott, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Endocrine (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: DEC b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 6
d. Total Number of Subjects Enrolled to Date: 6
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if TRH administration has any effect on serum levels of anpand, if so, whether this is a direct effect or due to the pressor response to TRH.

(16) Technical Approach: Various doses of TRH are given to normal volunteers on differenct days. After TRH administration blood is drawn for ANP levels and blood pressure and pulse are monitored continually.

(17) Progress: 6 subjects have been tested with one dose and no ANA response occured despite an increase in blood pressure. We are currenlty rechecking the samples and determining the performance characteristics of the assay kit. No progress FY 93.

FY94: There were no significant findings. There were, in my mind, questions about the accuracy and reproducibility of the ANP assay which may have affected our results.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Dec 93 (2) Protocol #: 92/113 (3) Status: Ongoing

(4) Title: Cyclosporine Treatment of Idiopathic Chronic Active Hepatitis

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: Dirk Davis, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators Kenneth Sherman, M.D.,PhD

(11) Key Words: cyclosporine hepatits

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Dec/Jun b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Multicenter trial to evaluate potential for cyclosporin as a therapeutic agent in steroid resistant autoimmune hepatitis.

(16) Technical Approach: Open label therapeutic trial of cyclosporin in patients with idiopathic chronic active hepatitis that is resistant to steroids and/or in patients who cannot tolerate standard immunosuppression methods.

(17) Progress: To date 7 patients with chronic active hepatitis have been enrolled with 4 of these at FAMC. All patients seemed to demonstrate a response. Among patients who completed at least 16 weeks of therapy, 5/7 were classified as responders as defined by normalization or near normalization of ALT. Of this group, two were non-compliant with therapy despite therapeutic respons. One was weaned from cyclosporine and prednisone and remains biochemically normal. One patient at UCHSC died.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Dec 93 (2) Protocol #: 92/114 (3) Status: Completed

(4) Title: Household Transmission of Hepatitis C Virus in Military Populations

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Kenneth Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: DEC b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 52
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Multicenter trial to determine prospective incidence of hepatitis C in family members of index cases.

(16) Technical Approach: Demographic/risk questionnaire with serial serum collection and testing for hepatitis C nucleic acid and antibodies.

(17) Progress: To date 23 patients with chronic active hepatitis attributable to viral hepatitis C have been enrolled at FAMC. Additionally, 53 family members of the index cases have agreed to participate. There have been no adverse events associated with this protocol. Enrollment is complete and participants are in 1-year followup phase.

Publications and Presentations: American Association for Liver Disease National Meeting, November, 1992.

Int Symposium on Viral Hepatitis, May 1992.

Detail Summary Sheet

(1) Date: 30 Sep 93 (2) Protocol #: 92/116 (3) Status: Ongoing

(4) Title: Early Detection of Second Primary Lung Cancers by Sputum Cytology Immunostaining

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Jerry Pluss, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Pul. Dis. (10) Associate Investigators

(11) Key Words: sputum, immunostaining, cancer

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 3
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Study usefulness of immunostaining cytology compared to regular sputum cytology, cxr and examination in the detection of recurrent lung cancer. This very high risk population is being used instead of cigarette smokers to obtain data on a smaller group of patients in a shorter time frame.

(16) Technical Approach: Yearly examination of high risk population that develops lung cancer. Using history, physical examination, cxr, induced sputums, non-induced sputums and bronchoscopy to evaluate cytologic methods (routine techniques, immuno staining techniques and other tumor markers).

(17) Progress: To date 54 patients are registered on this multi-center study with 12 from FAMC. Of the FAMC patients, 3 were found to have recurrent disease, and one paitent has moderate atypia. The second year of the study is complete and patients will need to be followed for one more year.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Feb 94 (2) Protocol #: 92/120 (3) Status: Ongoing

(4) Title: Prevalence of Gluten Sensitive Enteropathy in Patients with Insulin Dependent Diabetes Mellitus

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Peter McNally, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators

(11) Key Words:
celiae disease
diabetes

Dr. Davis
Dr. Merenich
Kenneth Sherman, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___FEB____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Prospective evaluation of the prevelance of GSE among type I IDDM patients.

(16) Technical Approach: Evaluation of the prevelance of GSE among type I IDDM patients.

(17) Progress: Demographics have been collected on 200 patients and lab draws done on 100 patients, within 1 week there will be 100 patients entered.

FY94: 20 pts/20 controls evaluated to date. Enrollment will continue to approximately 100.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Mar 94 (2) Protocol #: 92/123 (3) Status: Ongoing

(4) Title: A Double-Blind, Parallel-Group, Placebo-Controlled, Multicenter Study to Evaluate the Effect of Quinapril in Reducing Ischemic Events During a 3-Year Follow-up in Patients Post Intervention: QUIET (Quinapril Ischemic Event Trial). (IND) Parke-Davis Protocol 906-370

(5) Start Date: 1992 (6) Est Compl Date: 1996

(7) Principal Investigator: Richard Davis, COL, MC (8) Facility: FAMC

(9) Dept of MED/Cardiology (10) Associate Investigators Robert Cameron, LTC, MC Peter Bigham, MAJ, MC

(11) Key Words:
investigational new drug
ischemia
quinapril

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:__MAR/Sep_ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____15_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". See below.

(15) Study Objective: To test the effectiveness of an investigational new drug, quinapril, to prevent ischemic events post angioplasty or atherectomy.

(16) Technical Approach: Multi-center international trial---double-blind, randomized, placebo-controlled. Approximately 75 patients will be enrolled at FAMC and followed for a three-year period.

(17) Progress: It appears from data gathered at other institutions where subjects have been enrolled for some time that the placebo group requires recatheterization, while treadmills are negative on the active drug group. Enrollment closed 3 Feb 93, patients will be followed for two years.
FY94: Seven of the FAMC patients have discontinued from the study for the following reasons: CABG, pulmonary complications, murdered, lung cancer, renal dysfunction, CVA, inadvertently received Benazapril instead of the study drug, Quinapril, by the internal medicine resident. There have been a total of 21 adverse events reported from Denver General Hospital, University Hospital,

Continuation of Detail Summary Sheet for 92/123

Denver Veterans' AMC, and FAMC. Five of these events were from FAMC; 3 were cardiovascular related (2 unstable angina, 1 MI) and two were non-cardiovascular related (1 viral infection and 1 questionable lung mass). Amendment 6 "Substudy of the QUIET: Ace Gene Polymorphism in Coronary Artery Disease" was approved by the IRC on 7 Dec 93. The first followup patient will have blood drawn for the substudy on 8 Mar 94.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 1 Mar 94 (2) Protocol #: 92/125 (3) Status: Ongoing

(4) Title: The Relationship Between High Resolution Electrocardiography and Ventricular Ectopy in Hypertensive Patients with Left Ventricular Hypertrophy: A Pilot Study

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Richard Shea, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/Cardiology

(10) Associate Investigators

Mark Dorogy, MD
Aryo Oopick, MD
William Highfill, MD
David Boike, MD

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAR b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 12
d. Total Number of Subjects Enrolled to Date: 50
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To establish the relationship between echocardiographically determined LV mass, ectopy by Holter monitor, and abnormalities of the SAEIIG on hypertensive patients with LVH.

(16) Technical Approach: Prospective study of hypertensive patients. We obtain echo, Holter, and SAEIIG data and analyze in context of LV Mass vs percent of ectopy vs abnormal SAEIIG criteria.

(17) Progress: Enrollment continues at slower than predicted rate. Initial data suggests no relationship between LV mass and SAEIIG data, but more patients are needed. Negative results are still significant. Study design appears good. Results comparable to data available in literature.
FY94: Interim enrollment is complete with a total of 50 patients. Data analysis underway to determine if the study should continue.

Publications and Presentations: Interim results presented 05 Nov 92 at Army ACP meeting, Cardiology Section, by M. Dorogy.

Detail Summary Sheet

(1) Date: 5 Apr 94 (2) Protocol #: 92/127 (3) Status: Ongoing

(4) Title: A Phase III, Randomized Comparative Trial of ZDV versus ZDV plus ddI versus ZDV plus ddC in HIV-Infected Patients (NUCOMBO)

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: Wheaton Williams, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Inf. Dis. (10) Associate Investigators

(11) Key Words: HIV, ZDV,ddI, ddC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr/Nov b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 6
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To see if combining ddI or ddC with ZDV is more effective than ZDV alone in controlling HIV.

(16) Technical Approach: See protocol.

(17) Progress: Too early to compile any data on this study. No progress during this 6-month report period.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Apr 94 (2) Protocol #: 92/129 (3) Status: Terminated

(4) Title: Randomized Comparison of Radiation Versus Radiation Plus Continuous 5-Fluorouracil Infusion for Palliation of Bone Metastases: Phase II Study

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept of MED/Hem/Onc (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether better palliation of bone metastases and improved local control of tumor results from radiation plus continuous 5-Fu infusion compared to radiation alone.

(16) Technical Approach: Enroll at total of 42 patients, with 21 patients in each treatment group.

(17) Progress: Five patients enrolled to date, four of which were randomized to radiation alone. One patient has died. No patients currently on treatment. No conclusions about the treatment can be made. PI PCS.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 May 94 (2) Protocol #: 92/130 (3) Status: Ongoing

(4) Title: Antigen-Specific Immunoglobulin and Lymphocyte Responses in Systemic Lupus Erythematosus Patients Following Immunization with Three Clinically Relevant Vaccines

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator: Nicholas Battafarano, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Allergy (10) Associate Investigators
Michael Lieberman, LTC, MC
Raymond Enzenauer, MAJ, MC
Daniel F. Battafarano, MAJ, MC
Lawrence Larson, MAJ, MC
David Goodman, COL, MC

(11) Key Words:
lupus
systemic lupus erythematosus
immunizations

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 53
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine immunization responses in systemic lupus, erythematosus patients to develop practical immunization prescriptions for these patients.

(16) Technical Approach: Pre-immunization: Clinical evaluation immunoglobulin levels, lymphocyte responses; Immunize with pneumococcal, H. Influenza and test toxoid immunizations; Post-immunization: Clinical evaluation immunoglobulin levels, lymphocytes responses.

(17) Progress: Excellent - Patients have agreed to participate, 6 enrolled in test validation group, local injection inflammation has occurred as expected in a few patients. No difference in either group and all easily treated with tylenol, aspirin or NSAIDS. Symptoms score, red area at site of injection. **FY93:** The protocol was approved at BAMC with former FAMC AI, Daniel Battafarano, MAJ, MC, at BAMC with Steven Older, MAJ, MC, and Dennis Dyer, MAJ, MC, for a joint effort. During this reporting period 20 subjects were enrolled at FAMC for a total of 51, and 23 subjects enrolled at BAMC. FAMC 35/51 SLE completed; BAMC 0/23 are completed but will complete by May-July, 1993.
FY94: Since the last update a total of 79 patients were enrolled; 53 at FAMC and 25 at BAMC. 73 of those 79 complted the 3-month followup period; 48 at FAMC and 25 at BAMC. The results of the antigen-specific

antibody levels have been presented at two national meetings. However, the correlation of the responses with the other clinical and immunological variables still requires analysis. Some of the subjects will need followup evaluation on the basis of this analysis.

Publications:
ACR Abstract, "Antigen-Specific Antibody Responses in Lupus Patients Following Immunization." Arthritis Rheum 1993;36(9):S187.

Presentations:
American College of Rheumatology, 1993 Annual Meeting, Nov 93.
Harold Nelson Symposium, The 1994 Annual Meeting of the Association of Military Allergists, Feb 94.

Detail Summary Sheet

(1) Date: 7 Jun 94 (2) Protocol #: 92/132 (3) Status: Terminated

(4) Title: Aspects of Alveolar Macrophage Function During HIV Infection

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Daniel Ouellette, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Pulmonary Disease (10) Associate Investigators

(11) Key Words: HIV, macrophage, immunology Mark Ptaskiewicz, CPT, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JUNE b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Investigate the role of intracellular adhesion molecules in the development of HIV infection.

(16) Technical Approach: Measure levels of ICAM-1 in BAL fluid in HIV infected patients and in controls bronchoscoped for other reasons.

(17) Progress: Assay refinement almost completed. Will begin to enroll study patients in 4-6 weeks. FY94: Eight subjects have had bronchoscopy performed and specimens obtained for analysis. Results of analyses are pending. One patient had a fever in the 24-hr period following bronchoscopy and was admitted to hospital. Fever and clinical course were attributed to progression of Kaposi's sarcoma of the lung. The PI will PCS in Aug 94 at which time the protocol will be terminated.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 92/138 (3) Status: Ongoing

(4) Title: A Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study of the Use of Weekly Azithromycin as Prohylaxis Against the Development of Mycobacterium Avioum Complex (MAC) Disease in HIV-Infected People

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Wheaton Williams, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Inf.Dis. (10) Associate Investigators

(11) Key Words:
HIV
MAC
azithromycin

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the safety and efficacy of oral azithromycin administered once a week in the prevention of disseminated MAC in severely immunocompromised HIV infected patients with a CD4 cell count of <100/mm.

(16) Technical Approach: See protocol.

(17) Progress: Of 15 patients screened 11 were randomized to Rx/placebo; three chose not to continue; one was MAC+ - failed screen; one waiting for screen cultures to qualify. Pfizer doing analysis on data to 30 Apr 94.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 Aug 94 (2) Protocol #: 92/141 (3) Status: Completed

(4) Title: The Relationship of Gout and Hyperuricemia to Hypothyroidism

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Alan Erickson, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/INT.MED.

(10) Associate Investigators

Raymond Enzenauer, MD
John Merenich

(11) Key Words:
gout
hypothyroidism

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: AUG b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 72
d. Total Number of Subjects Enrolled to Date: 75
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To survey the relationship of gout and hypothyroidism.

(16) Technical Approach: Retrospective and prospective review.

(17) Progress: The retrospective and prospective portions of the study are completed. To date 73 subjects enrolled, 72 this report period.

Publications and Presentations: FY94: The research is scheduled for publication in the Am J Med in Fall, 1994.

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 92/142 (3) Status: Ongoing

(4) Title: Clarithromycin in Combination with Omeprazole or Omeprazole as a Single Agent for the Treatment of Patients with Duodenal Ulcers

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators

MAJ Steven Hammond
MAJ Scot Lewey
LTC Milton Smith

(11) Key Words:
duodenal ulcer

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 7
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if omeprazole plus clarithromycin is more effective in preventing ulcer recurrence than omeprazole plus placebo.

(16) Technical Approach: Double blind randomized multi-center trial with endoscopic followup for recurrence.

(17) Progress: No patients enrolled to date; still awaiting FDA approval; anticipate start 1 Sep 93.

FY94: Two patients continue in final followup phase. No further enrollment.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 92/144 (3) Status: Ongoing

(4) Title: Double-Dummy, Double-Blind, Randomized, Single-Center Study on the Effect of Hormone Replacement Therapy on Blood Pressure

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator:
William Georgitis, COL, MC

(8) Facility: FAMC

(9) Dept of MED/Endocrine

(10) Associate Investigators
Shirley Spencer, Ped Pharm

Rhonda Wagner, CPT, AN

(11) Key Words:
hormone replacement
blood pressure

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 18
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine estrogen replacement therapy effects on blood pressure in post menopausal women.

(16) Technical Approach: This is a 6-month study of 100 women assinged to either Premarin 0.625mg/day, placebo shoulder patch; or Estraderm 0.05mg patch, placebo pill/day. Blood, urine and blood pressure will be monitored.

(17) Progress: To date 18 patients enrolled. One patient dropped out secondary to rash induced by patch adhesive and spotting.

FY94: Subject enrollment continues at a slower rate than expected, 50 to date, may require one year more to enroll a total of 100 subjects.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Oct 93 (2) Protocol #: 93/103 (3) Status: Ongoing

(4) Title: A Randomized, Comparative, Prospective Study of Daily Trimethoprim/Sulfamethoxazole (TMS) and Thrice Weekly TMS for Prophylaxis Against PCP in HIV-Infected Patients

(5) Start Date: Oct 92 (6) Est Compl Date: 1994

(7) Principal Investigator: (8) Facility: FAMC
Wheaton Williams, MAJ, MC

(9) Dept of Med/Infect Dis (10) Associate Investigators

(11) Key Words:
HIV, prophylaxis, PCP, trimethoprim, sulfamethoxazole

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Oct b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: None
d. Total Number of Subjects Enrolled to Date: None
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To evaluate the safety and efficacy of two dose regimens (daily or 3x a week) of Trimethoprim/Sulfamethoxazol (TMP/SMX) in the prevention of Pneumocystis carinii pneumonia (PCP) in high-risk HIV-infected patients.

(16) Technical Approach: There will be two drug regimens, TMP/SMX daily or 3x a week (Monday, Wednesday and Friday). Patients will be assigned therapy according to a prepared randomization schedule.

(17) Progress: No patients enrolled.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 5 Oct 93 (2) Protocol #: 93/104 (3) Status: Ongoing

(4) Title: A Randomized, Prospective, Double-Blind Study Comparing Fluconazole with Placebo for Primary and Secondary Prophylaxis of Mucosal Candidiasis in HIV-Infected Women (CPCRA 010)

(5) Start Date: Oct 92 (6) Est Compl Date: 1995

(7) Principal Investigator: Wheaton Williams, MAJ, MC (8) Facility: FAMC

(9) Dept of Med/Infect Dis (10) Associate Investigators

(11) Key Words:
HIV, prophylaxis, Candidiasis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Oct b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: None
d. Total Number of Subjects Enrolled to Date: None
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To evaluate the efficacy of Fluconazole vs. placebo for the prevention of Candida esophagitis and vaginal/oropharyngeal candidiasis in HIV-infected women.

(16) Technical Approach: Patients will be assigned one of the two drug regimens, Fluconazole or placebo weekly, according to a prepared randomization schedule.

(17) Progress: None

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 93/105 (3) Status: Ongoing

(4) Title: Amlodipine Study of the Angina Population

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Tally Culclasure, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Cardiology

(10) Associate Investigators
Brian Horvath, MAJ, MC
Mike McBiles, LTC, MC

(11) Key Words:
Amlodipine, angina, IND

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___Nov____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine safety and efficacy of amlodipine as replacement therapy for other antianginal medications in patients with chronic angina.

(16) Technical Approach: Randomized, double-blind, placebo controlled, multi-center trial. Ten subjects per site. Phase I baseline 4 weeks; Phase II is 4 weeks of taper-off heart medication period, then assignment to study drug treatment for 4 weeks; Phase III is an optional 3 month treatment on open label.

(17) Progress: None. CIRO approved 2 Sep 93

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Dec 93 (2) Protocol #: 93/111 (3) Status: Ongoing

(4) Title: An Open Protocol for the Use of Agrelin (Anagrelide) for Patients with Thrombocythemia

(5) Start Date: 1993 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Daniel Tell, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Hem/Onc

(10) Associate Investigators
Patrick Judson, LTC, MC
David Faragher, MAJ, MC

(11) Key Words:
IND, anagrelide,
thrombocytopenia

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if anagrelide is a safe and effective treatment to reduce the number of platelets in the blood. This is also a dose ranging study.

(16) Technical Approach: Open label study, 3-month supply of drug in 0.5 mg and 1.0 mg capsules.

(17) Progress: One patient was enrolled but was taken off study due to non-compliance.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Dec 93 (2) Protocol #: 93/112 (3) Status: Ongoing

(4) Title: A Phase I-II Study of Daily Carboplatin and Simultaneous Accelerated Hyperfractionated Chest Irradiation Followed by Single Agent Carboplatin in Patients with Regionally Inoperable (Stages IIIa and IIIb) Non-Small Cell Lung Cancer

(5) Start Date: 1993 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Hem/Onc (10) Associate Investigators

(11) Key Words:
carboplatin, radiation therapy
lung cancer

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To improve response rates by combining radiation therapy (standard treatment) with carboplatin chemotherapy and to study the side effects of this treatment

(16) Technical Approach: Initial treatment is daily chest irradiation and intravenous carboplatin chemotherapy (except on weekends) for four weeks. Rest period of 3-4 weeks between three cycles of treatment.

(17) Progress: No progress.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Dec 93 (2) Protocol #: 93/113 (3) Status: Ongoing

(4) Title: A Pilot Phase II Study of Induction Therapy with Daily Etoposide, Daily Cisplatin and Simultaneous Chest Irradiation Followed by Four Cycles of Consolidation Cisplatin/Etoposide Therapy in Limited Stage Small Cell Lung Cancer

(5) Start Date: 1993 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daneil Tell, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Hem/Onc (10) Associate Investigators

(11) Key Words:
lung cancer, etoposide,
cisplatin, radiation therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate a new combination of this standard treatment.

(16) Technical Approach: Per University of Colorado Cancer Center Clinical Trial Protocol.

(17) Progress: No progress.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 93/114 (3) Status: Ongoing

(4) Title: Parathyroid Hormone-Related Peptide in Connective Tissue Disease

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Arnold Asp, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Endo

(10) Associate Investigators
LTC Arnold Asp
MAJ James Singleton
CPT Matthew Schofield

(11) Key Words:
connective tissue disease

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 13
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if PTH&P levels are elevated in connective tissue disease.

(16) Technical Approach: Open, repeated measures comparison of controls, rheumatoid arthritis and scleroderm patients.

(17) Progress: Thirteen subjects of projected 63 total obtained.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 22 Apr 94 (2) Protocol #: 93/120 (3) Status: Completed

(4) Title: A Comparative Trial of 256U87 and Acyclovir for the Treatment of First-Episode Genital Herpes Infection (IND)

(5) Start Date:1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Kathleen David-Bajar, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Derm.

(10) Associate Investigators
Scott D. Bennion, COL, MC
Richard Gentry, COL, MC
James Fitzpatrick, COL, MC

(11) Key Words:
primary herpes simplex
infections of the genitals

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Feb b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. Three adverse reactions: (1) vertigo, from 1/27/94-1/28/94, classified as severe but not serious, possibly attributable to study medicaton. The patient had a history of vertigo, and responded rapidly to meclizine given by mouth. She elected not to discontinue the study medication. (2) maxillary fullness, from 1/27/94 to 1/27/94, classified as mild and not serious, not reasonably attributable, with no action taken, and the code was not broken; (3) diarrhea, from 1/30/94 to 1/30/94, classified as mild and not serious, not reasonably attributable, with no action taken and the code was not broken.

(15) Study Objective: To compare the efficacy and safety of 256U87 with acyclovir in the treatment of first-episode genital herpes infection of immunocompetent patients.

(16) Technical Approach: Patients presenting to the clinic within 3 days (72 hours) of lesion onset with signs/symptoms consistent with first-episode genital herpes are entered after informed consent is obtained. Lesions will be swabbed and cultured for the presence of herpes simplex virus. supernatant fluid from the initial viral culture will be sent to BW Co. for determination of acyclovir sensitivity as part of a surveillance study of viral resistance. Patients will be equally randomized to one of two treatment groups: Group A: 256U87 1000mg orally 2x/day for 10 days; Group B: Acyclovir 200mg orally 5x/day for 10 days. Patients will be frequently evaluated with

clinical and laboratory exams throughout a 14 day examination period or until all lesions have healed.

(17) Progress: FY94: Ten patients have been entered thus far, and no significant problems have been encountered. The study is now complete; however, data is not yet available.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Feb 94 (2) Protocol #: 93/121 (3) Status: Ongoing

(4) Title: Outpatient Screening for Sleep Apnea

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Hai Bui, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/

(10) Associate Investigators
William Reed, MAJ, MC

(11) Key Words:
sleep apnea,
screening method

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Feb b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Develop an inexpensive, convenient method of screening for sleep apnea.

(16) Technical Approach: Record patients.

(17) Progress: Awaiting software sound recording translator.

FY94: Have acquired software for digital sound recording and are proceeding to enroll patients.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Apr 94 (2) Protocol #: 93/128 (3) Status: Ongoing

(4) Title: The Efficacy of a Standardized Acupuncture Regimen and Amitriptyline compared with Placebo as a Treatment for Pain Caused by Peripheral Neuropathy in HIV-Infected Patients (CPCRA 022)

(5) Start Date: Apr 93 (6) Est Compl Date: 1995

(7) Principal Investigator: Wheaton Williams, MAJ, MC (8) Facility: FAMC

(9) Dept of Med/Infect Dis (10) Associate Investigators Jeffrey Casserly, PA-C

(11) Key Words: HIV, acupuncture, amitriptyline, neuropathy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr/Oct b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the separate and combined efficacy of a standardized acupuncture regimen and amitriptyline on the relief of pain due to HIV-related peripheral neuropathy and on the quality of life of HIV-infected patients.

(16) Technical Approach: Randomized, modified double-blind, 2x2 factorial, multicenter clinical trial. Patients will be treated for 14 weeks. There will be a 4-week post treatment followup to assess short term relief of pain. Patients will be randomized according to schedules prepared to ensure an approximate allocation ration of 1:1:1:1. Use of amitriptyline or placebo will be double-blind. Although the acupunturist cannot be blinded to acupuncture or alternate point treatment, the patient will be blinded (modified double-blind design).

(17) Progress: The protocol was amended 1 Jun 93. One subject enrolled since FY93 APR.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Apr 94 (2) Protocol #: 93/129 (3) Status: Ongoing

(4) Title: A Randomized, Comparative, Placebo-Controlled Trial of the Safety and Efficacy of Oral Ganciclovir for Prophylaxis of Cytomegalovirus (CMV) Retinal and Gastrointestinal Mucosal Disease in HIV-Infected Individuals with Severe Immunosuppression. CPCRA 023.

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator: Wheaton Williams, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Inf. Dis. (10) Associate Investigators

(11) Key Words:
cytomegalovirus (CMV)
ganciclovir

Robert H. Gates, LTC, MC
Jeffrey Casserly, PA-C

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr/Oct b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the safety and efficacy of oral ganciclovir for prophylaxis against CMV retinal and gastrointestinal mucosal disease in HIV-infected patients with severe immunosuppression.

(16) Technical Approach: See protocol.

(17) Progress: One subject was enrolled since the last 6-month review.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Apr 94 (2) Protocol #: 93/130 (3) Status: Ongoing

(4) Title: Calcitonin Response to Pentagastrin Stimulation Testing After Near-Total Thyroidectomy and Radioactive Iodine Ablation

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Arnold A. Asp, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Endocrine

(10) Associate Investigators
Michael Rensch, CPT, MC
Michael McDermott, LTC, MC
William Georgitis, COL, MC

(11) Key Words:
radioactive iodine
medullary carcinoma
thyroid

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: to establish a range of stimulated calcitonin valves following near-total thyroidectomy and determine the effect of radioactive iodine upon these values.

(16) Technical Approach: Open, repeated measures prospective study.
(17) Progress: Two patients enrolled; calcitonin batched and performed anually. Investigators were changed since the FY93 Annual Progress Report, and one new subject enrolled.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Apr 94 (2) Protocol #: 93/131 (3) Status: Ongoing

(4) Title: A Retrospective Evaluation of the Use of the Bard Liver Biopsy Needle: Adequacy of Specimens and Complications

(5) Start Date: 1993 (6) Est Compl Date: 30 Jun 94

(7) Principal Investigator: Spencer Root, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators

(11) Key Words: bard liver biopsy needle Kenneth E. Sherman, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: We will attempt to quantitatively evaluate biopsy parameters and objectively determine comparative efficacy of the Bard Monopty needle to standard liver biopsy methods.

(16) Technical Approach: To anlayze the biopsy size, quality and types of complications associated with these 18g needles. There are no safety concerns associated with this study as it will be retrospective and involve only records review.

(17) Progress: Review charts, the study is ongoing. There has been some delay in completion of the chart review due in part to some difficulatin in obtaining documents necessary to complete the review.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/135A (3) Status: Ongoing

(4) Title: Gastroenterologic Service Training Using Laparoscopic Techniques in the Swine (Sus Scrofa)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Peter R. McNally, LTC, MC

(9) Dept of MED/Gastro. (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IACUC Review: Apr b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Facilitate training of residents/fellows, nurses in laparoscopy.

(16) Technical Approach: Animal model to simulate human surgery.

(17) Progress: Bi-annual labs have been conducted; study very successful, wish to continue bi-annual.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 May 94 (2) Protocol #: 93/136 (3) Status: Ongoing

(4) Title: A Double-Blind, Randomized, Multi-Dose, Placebo-Controlled, Parallel Group Dose Ranging Study to Evaluate the Effects of MK-0591 in Induction of Symptomatic and Endoscopic Remission in Patients with Active Mild to Moderate Ulcerative Colitis. IND#41-060 (MK-0591; Protocol #024-00) AND Amendment #1 (MK-591; Prot No 024-01 And addendum "Open Label-Extension Study to Evaluate the Safety and Tolerability of MK-0591 for 12 months in Patients with Mild to Moderate Ulcerative Colitis".

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators
MAJ Robert Sudduth
MAJ Dirk Davis
MAJ Scot Lewey
MAJ Spencer Root
MAJ Steve Hammond
MAJ Thomas Kepczyk
LTC Milton Smith
Laura Farber, RN
Sofia DeAngelis, RN

(11) Key Words:
IND
ulcerative colitis

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___May____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The study is to determine if MK-0591, an investigational drug, is safe and effective in the treatment of ulcerative colitis.

(16) Technical Approach: Per protocol.

(17) Progress: New study. FY94: Enrolled five total; 3 now in open label continuation. Multiple amendments, addendums, advertising materials, changes of investigators occurred since the study was originally approved. AE reported, see IRC minutes Mar 94. Amendment 2 and addendum IRC approved 20 Jul 93; Amendment 3 IRC approved 5 Oct 93.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 May 94 (2) Protocol #: 93/137 (3) Status: Ongoing

(4) Title: Aspirin in the Prevention of Neoplastic Polyps--A MultiCenter Study

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators
Sophia DeAngelis, RN
Spencer Root, MAJ, MC
Robert Sudduth, MAJ, MC
Dirk Davis, MAJ, MC
Stephen Lawrence, MAJ, MC

(11) Key Words:
neoplastic polyps

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To investigate the efficacy of aspirin in preventing the recurrence of neoplastic polyps of the large bowel.

(16) Technical Approach: Conduct a randomized, double-blind, placebo-controlled clinical trial. Test the hypothesis that aspirin taken orally will reduce the occurrence of neoplastic polyps among those patients with a recent history of these tumors.

(17) Progress: New study. FY94: No patients enrolled to date. Still awaiting funding from NCI. Anticipate enrollment to start in Jun-Jul 94.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 93/138 (3) Status: Ongoing

(4) Title: A Screening Study for Myocardial Sarcoidosis Comparing Transesophageal Echocardiography, Transthoracic Echocardiography, Electrocardiography, Gallium-67 Scintigraphy and 99mTcSestamibi Scintigraphy

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator: David Schacter, CPT, MC (8) Facility: FAMC

(9) Dept of MED/Cardiology (10) Associate Investigators

Mike McBiles, LTC, MC

(11) Key Words:
sarcoid
electrocardiography
gallium, sestamibi

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 13
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Assess most effective non-invasive test for detecting sarcoidosis in the heart.

(16) Technical Approach: Compare electrocardiography, transthoracic and transeophageal echocardiography, gallium-67 and 99mTc sestamibi scintigraphy.

(17) Progress: No notable difference among electrocardiography and echocardiography. Still await results of both scintigraphy.

Publications: Abstract, Jul 94, Chest;

Presentation: Am College of Chest Physicians, New Orleans, FY94.

Detail Summary Sheet

(1) Date: 3 May 94 (2) Protocol #: 93/139 (3) Status: Completed

(4) Title: The Presence of HOuse Dust Mite Antigens in Colorado Homes Utilizing Evaporative Coolers: A Multicenter Study

(5) Start Date: 5/93 (6) Est Compl Date: 9/93

(7) Principal Investigator:
Amy Ellingson, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/Allergy

(10) Associate Investigators
Robert LeDoux, BS
P.K. Vedanthan, MD
Richard W. Weber, MD

(11) Key Words:
dust mite
prevalence
humidity

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 38
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To study the prevlaence of home dust mite antigen in Colorado homes utilizing evaporate coolers.

(16) Technical Approach: Collect samples of dust from 20 homes in Colorado which use swamp coolers during May and again in August. Analysis of dust extracts for specific HDM antigen (Der P1 & Der f1) using a monoclonal antibody in a sandwich ELISA.

(17) Progress: We have collected all the samples, extracted them and just completed the ELISAs. Currently the data is being analyzed. An abstract is being submitted to the American Academy of Allergy & Immunology for the national meeting in March 1994. FY94: Completed.

Publications:
Abstract published JACI Jan 94.

Presentations:
Harold Nelson Symposium, 1 Feb 94.
AAAI annual meeting, 5 Mar 94.

Detail Summary Sheet

(1) Date: 7 Jun 94 (2) Protocol #: 93/140 (3) Status: Completed

(4) Title: A Study to Investigate the Efficacy and Safety of Oral valacyclovir (1000 mg or 500 mg, Twice Daily) Compared with Placebo in the Treatment of Recurrent Genital Herpes in Immunocompetent Patients

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Kathleen David-Bajar, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Derm.

(10) Associate Investigators
Scott D. Bennion, COL, MC
Richard Gentry, COL, MC
James Fitzpatrick, COL, MC

(11) Key Words:
recurrent herpes simplex
infections of the genitals

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jun b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare the efficacy and safety of two different doses of valacyclovir (1000mg twice daily, or 500mg twice daily) compared to placebo in immunocompetent patients with frequently recurring genital herpes simplex virus infections.

(16) Technical Approach: Immunocompetent patients with frequently recurring genital herpes simplex virus infections will be randomized according to a 3:3:2 randomization, such that for the total of 640 patients (from all centers), 240 will receive 100mg of valacyclovir twice daily, 240 will receive 500mg of valacyclovir twice daily, and 160 patients will receive placebo twice daily for 5 days. After being entered into the study, patients will self-initiate therapy at the first sign of symptom of an HSV infection recurrence, and continue the study medication for 5 days. Beginning within the first 24 hours of starting the study medication, and continuing until all lesions are healed, the patients will be examined frequently, with cultures taken from their lesions, and laboratory tests monitored.

(17) Progress: Fourteen patients were entered with seven patients experiencing breakouts and completing the study. No relevant, drug-specific adverse effects have been noted. No data regarding efficacy is yet available, as all codes are still unbroken.
Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Jun 94 (2) Protocol #: 93/141 (3) Status: Ongoing

(4) Title: A Controlled Trail of Implantable Cardiac Defibrillators Versus Medical Anti-Arrhythmic Drug Therapy

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Richard Davis, COL, MC (8) Facility: FAMC

(9) Dept of MED/Cardiology (10) Associate Investigators Koonlawee Nademanee, MD, (PI, DGH)

(11) Key Words: cardiac defibrillator

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jun b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether ICD placement reduces total mortality when compared to conventional antiarrhythmic drug therapy. Secondary objectives include an economic assessment of the relative cost-effectiveness of the alternative treatment options and a quality-of-life evaluation.

(16) Technical Approach: 200 patients will be recruited for the pilot and a total of at least 1,000 patients recruited for the full-scale trial. The patients will be recruited at FAMC and referred to Dr. Nademanee for enrollment in the study.

(17) Progress: FY94: Four patients were enrolled to date, one from FAMC. One adverse event was reported for exacerbation of congestive heart failure. The subject was implanted with ICD and managed on amiodarone by his private cardiologist. This event was not thought to be study drug related. The pilot portion of the study complete, and safety and efficacy data will be reviewed in June 1994 to see if data warrants a full scale trial.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 93/142 (3) Status: Ongoing

(4) Title: Hypertension Optimal Treatment International Study

(5) Start Date: 1993 (6) Est Compl Date: 1996

(7) Principal Investigator:
Jane Yeun, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Nephrology

(10) Associate Investigators

(11) Key Words:
hypertension
diastolic blood pressure
optimal blood pressure

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 25
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine optimal diastolic blood pressure goal and if ASA is efficacious in hypertensive patients.

(16) Technical Approach: Patients randomized to 3 BP goals, 90, 85, 80 mm Hg diastolic. Patients also randomized to ASA vs placebo. Endpoints cardiovascular events and death.

(17) Progress: Protocol recently approved, in process of enrolling patients.
FY94: Closed to subject enrollment 30 Apr 94, 25 enrolled. Blood pressure will be monitored at 1-3 month intervals.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 93/143 (3) Status: Ongoing

(4) Title: Does Gastroesophageal Reflux Induce Myocardial Ischemia?

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
George Winters, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/GI

(10) Associate Investigators

Peter McNally, LTC, MC
Mike McBiles, LTC, MC

(11) Key Words:
gastroesophageal reflux
myocardial ischemia

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jul/Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if esophageal acid infusion induces myocardial ischemia; (2) to determine the nature of cardiovascular responses (if any) to gastroesophageal reflux simultated by esophageal acid infusion; (3) to correlate patient symptoms with objective findings.

(16) Technical Approach: Patients will be assigned per study algorithm to recreate the conditions found in gastroesophageal reflux in order to see what affects it may have on the heart.

(17) Progress: Approved in Aug 93 by the IRC as a 10-subject pilot. No progress to date. FY94: Having trouble recruiting subjects, two enrolled to date. Equipment breakdown should be fixed soon. Protocol exclusion criteria amended 5 Jul 94.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 93/144 (3) Status: Terminated

(4) Title: A Comparison of Ranitidine 300 mg BID, Ranitidine 150 mg BID and Placebo in the Treatment of Aspirin or Nonsteroidal Anti-Inflammatory Drug Associated Gastric Ulcers in Patients with Osteo- or Rheumatoid Arthritis. (IND GLAXO RAN-481)

(5) Start Date: Oct 93

(6) Est Compl Date: Sep 94

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of Med/GI

(10) Associate Investigators
Sterling West, COL, MC
Milton Smith, MD
Robert Sudduth, MAJ, MC
Thomas Kepczk, MAJ, MC, et al

(11) Key Words:
Ranitidine, NSAID, ulcers, arthritis,IND

(12) Accumulative MEDCASE:
Refer to Unit Summary Sheet of this Report.

(13) Est Accum OMA Cost:

(14) a. Date, Latest IRC Review: Sep b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: *
d. Total Number of Subjects Enrolled to Date: *
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Efficacy and safety.

(16) Technical Approach: As per title, randomized, double-blinded IND study, 10 patients to be enrolled over 15 months, drug administration for 12 weeks, four endoscopies and quality of life and ecomonic questionnaires.

(17) Progress: Study recently approved by IRC; CIRO approval pending.

FY94: Study withdrawn by sponsor.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 93/145 (3) Status:Terminated

(4) Title: A Comparison of Ranitidine 150 mg BID and Placebo in the Treatment of Aspirin or Nonsteroidal Anti-Inflammatory Drug Associated Duodenal Ulcers in Patients with Osteo- or Rheumatoid Arthritis. (IND GLAXO RAN-482)

(5) Start Date: Oct 93 (6) Est Compl Date: Sep 94

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of Med/GI

(10) Associate Investigators
Sterling West, COL, MC
Milton Smith, MD
Robert Sudduth, MAJ, MC
Thomas Kepczk, MAJ, MC, et al

(11) Key Words:
Ranitidine, NSAID, ulcers, arthritis,IND

(12) Accumulative MEDCASE:
Refer to Unit Summary Sheet of this Report.

(13) Est Accum OMA Cost:

(14) a. Date, Latest IRC Review: Sep b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: *
d. Total Number of Subjects Enrolled to Date: *
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Efficacy and safety.

(16) Technical Approach: As per title, randomized, double-blinded IND study, 10 patients to be enrolled over 15 months, drug administration for 12 weeks, four endoscopies and quality of life and ecomonic questionnaires.

(17) Progress: Study recently approved by IRC; CIRO approval pending.

FY94: Study withdrawn by sponsor.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 93/146 (3) Status: Terminated

(4) Title: A Comparison of Ranitidine 300 mg BID, Ranitidine 150 mg BID and Placebo for Prophylaxis of Aspirin or Nonsteroidal Anti-Inflammatory Drug Associated Gastric Ulcers in Patients with Osteo- or Rheumatoid Arthritis and NO History of Gastric or Duodenal Ulcer Duodenal Ulcer. (IND GLAXO RAN-498)

(5) Start Date: Oct 93

(6) Est Compl Date: Sep 94

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of Med/GI

(10) Associate Investigators
Sterling West, COL, MC
Milton Smith, MD
Robert Sudduth, MAJ, MC
Thomas Kepczk, MAJ, MC, et al

(11) Key Words:
Ranitidine, NSAID, ulcers, arthritis,IND

(12) Accumulative MEDCASE:
Refer to Unit Summary Sheet of this Report.

(13) Est Accum OMA Cost:

(14) a. Date, Latest IRC Review: Sep b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: *
d. Total Number of Subjects Enrolled to Date: *
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Efficacy and safety.

(16) Technical Approach: As per title, randomized, double-blinded IND study, 10 patients to be enrolled over 15 months, drug administration for 12 weeks, four endoscopies and quality of life and ecomonic questionnaires.

(17) Progress: Study recently approved by IRC; CIRO approval pending.

FY94: Study withdrawn by sponsor.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 93/147 (3) Status: Terminated

(4) Title: A Comparison of Ranitidine 300 mg BID, Ranitidine 150 mg BID and Placebo for Prophylaxis of Aspirin or Nonsteroidal Anti-Inflammatory Drug Associated Gastric Ulcers in Patients with Osteo- or Rheumatoid Arthritis and a History of Gastric or Duodenal Ulcer. (IND GLAXO RAN-499)

(5) Start Date: Oct 93 (6) Est Compl Date: Sep 94

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of Med/GI

(10) Associate Investigators
Sterling West, COL, MC
Milton Smith, MD
Robert Sudduth, MAJ, MC
Thomas Kepczk, MAJ, MC, et al

(11) Key Words:
Ranitidine, NSAID, ulcers, arthritis,IND

(12) Accumulative MEDCASE:
Refer to Unit Summary Sheet of this Report.

(13) Est Accum OMA Cost:

(14) a. Date, Latest IRC Review: Sep b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Efficacy and safety.

(16) Technical Approach: As per title, randomized, double-blinded IND study, 10 patients to be enrolled over 15 months, drug administration for 12 weeks, four endoscopies and quality of life and ecomonic questionnaires.

(17) Progress: Study recently approved by IRC; CIRO approval pending.

FY94: Study withdrawn by sponsor.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 93 (2) Protocol #: 93/148 (3) Status: Ongoing

(4) Title: Patient Utilities for Screening with Flexible Sigmoidoscopy

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
William Reed, MAJ, MV

(8) Facility: FAMC

(9) Dept of MED/Int. Med.

(10) Associate Investigators
Michael J. Weaver, COL, MC

(11) Key Words:
utility assessment, sigmoidoscopy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___Nov____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine utility assessments for screening flexible sigmoidoscopy for several patient and physician groups. Our secondary objectives are to determine whether demographic factors influence utility assessment, to asses show published decision analyses on screening sigmoidoscopy will be affected, and to assess test-retest reliability of our methods over a three month period.

(16) Technical Approach: In addition to obtaining demographic information from subjects, we will use the techniques of the standard reference gamble and time tradeoff. Will assess the risk they are willing to take to avoid a lifelong protocol of regular screening flexible sigmoidoscopy. We hope to repeat the utility assessments approximately three months after the initial interview.

(17) Progress: New study.

Publications and Presentations: None

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-100

A Prospective Controlled Trial of the Efficacy of Maloney Versus Through-the-Scope Hydrostatic Balloon Dilators in the Treatment of Benign Esophageal Strictures

START DATE: Oct 93 EST COMP DATE: Oct 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: Oct 93 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: balloon dilator, Maloney, esophageal strictures

OBJECTIVE: To determine whether one type of dilator is better than another type for the treatment of benign esophageal strictures.

TECHNICAL APPROACH: Randomize up to 100 subjects to the dilators; perform interim analysis after 50 subjects.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None

Summary of prior and current progress: No progress. Original PI PCS'd. Will investigate addition of new collaborators or possibly change to multicenter (MAMC;TAMC)

PUBLICATIONS: None

PRESENTATIONS: None

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-101

SWOG 9043 Phase III Randomized Trial of Beta Carotene Plus Low Dose Retinol vs Placebo in Prevention of Second Primaries in Stage I and II Head and Neck Cancer

START DATE: Oct 93 EST COMP DATE: Oct 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Daniel Tell, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Hem-Onc

ASSOCIATE INVESTIGATORS: None

PERIODIC REVIEW DATE: Jan 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: beta carotene, head and neck cancer

OBJECTIVE: To determine patient response to treatment with beta carotene (a nutritional agent related to vitamin A) in prevention of secondary tumors of the oral cavity.

TECHNICAL APPROACH: Approximately 5 patients at FAMC will be randomized to receive either placebo or beta carotene (30 mg/day) for 5 years. Blood specimens will be monitored and questionnaires given related to tobacco, alcohol and vitamin use.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: None to date.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-102

SWOG 9110 A Phase II Evaluation of Didemnin B in Central Nervous System Tumors

START DATE: Oct 93 EST COMP DATE: Oct 98 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Daniel Tell, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Hem-Onc

ASSOCIATE INVESTIGATORS: None.

PERIODIC REVIEW DATE: Jan 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: didemnin B, CNS tumors

OBJECTIVE: To determine the response and length of time of improvement of patients with central nervous system tumors when treated with didemnin B as a single agent and to define the side effects of this drug.

TECHNICAL APPROACH: Single agent treatment by IV with didemnin B every 28 days until disease progresses.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: None to date. Study temporarily closed.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-103

The Effect of Oral D-Sotalol on Mortality in Patients with Atherosclerotic Coronary Heart Disease and Left Ventricular Dysfunction "SWORD" Survival with Oral D-Sotalol. (IND #23,933)

START DATE: Dec 93 EST COMP DATE: Dec 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Mitchel Kruger, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Card

ASSOCIATE INVESTIGATORS: Tally Culclasure, CPT, MC, Ann Richardson, RN

PERIODIC REVIEW DATE: Nov 93 REVIEW RESULTS: Continue
FUNDING: FACT
GIFTS: Bristol-Myers, IND drug & placebo

KEY WORDS: D-sotalol, atherosclerotic heart disease, left ventricular dysfunction

OBJECTIVE: To determine if oral d-sotalol reduces the risk of death in patients who had a myocardial infarction and have left ventricular dysfunction.

TECHNICAL APPROACH: Approximately 20-30 adult patients will be randomized to placebo or d-sotalol 100 mg BID for the first 7 days. If tolerated, the dose will be increase to d-sotalol 200 mg or placebo BID for the remainder of the study.

PROGRESS:

Number of subjects enrolled to date: 2
Number of subjects enrolled for reporting period: 2
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Entrance criteria are very strict. Many patients are not eligible due to creatinine clearance restrictions.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-104

Detection of Measles Virus in Tissue Samples from Patients with Crohn's Disease by Polymerase Chain Reaction (PCR) Testing

START DATE: Nov 93 EST COMP DATE: Nov 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Scot Lewey, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Kenneth Sherman, MAJ, MC, John Singleton, MD

PERIODIC REVIEW DATE: Nov 93 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: measles virus, Crohn's Disease, polymerase chain reaction testing

OBJECTIVE: To confirm the presence or absence of Measles virus RNA in tissue samples from subjects with Crohn's Disease as compared to controls without inflammatory bowel disease.

TECHNICAL APPROACH: Pilot study of 10 adult patients undergoing diagnostic colonoscopy with biopsy for other indications will be tested using PCR assay.

PROGRESS:

Number of subjects enrolled to date: 30
Number of subjects enrolled for reporting period: 30
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Ten Crohn's subjects; 10 control subjects; 10 ulcerative colitis subjects. The measles virus has been developed and validated with control samples of wild measles virus. Control samples of colonic tissue from normal volunteer subjects were tested with and without measles virus added. Initial five subjects each with Crohn's disease, ulcerative colitis and normal colon tissue were tested for presence of measles virus RNA by PCR. None had detectable measles virus RNA. Additional samples are to be tested.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-105

TREND (Trial on Reversing Endothelial Dysfunction: A 6-Month, Randomized, Double-Blind Study of the Effect of Quinapril on Endothelial Dysfunction in Coronary Arteries as Assessed by Serial Intracoronary Acetylcholine Challenge). IND#36,506

START DATE: Dec 93 EST COMP DATE: Sep 94 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Robert Cameron, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Card

ASSOCIATE INVESTIGATORS: Mark Dorogy, MAJ, MC

PERIODIC REVIEW DATE: Dec 93 REVIEW RESULTS: NA
FUNDING: NA
GIFTS: NA

KEY WORDS: NA

OBJECTIVE: To demonstrate the effect of the ACE inhibitor, quinapril, on a postulated early manifestation of atherosclerosis, endothelial dysfunction, in patients scheduled for PTCA or atherosclerosis and with at least one angiographically normal coronary artery.

TECHNICAL APPROACH: NA

PROGRESS:

Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Sponsor terminated participation at FAMC due to the small number of subjects enrolled in the dependent study, 93/102.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-106

A Multicenter, Double-Blind, Randomized Dose Ranging Study to Evaluate the Effects of Omeprazole Co-administered with Amoxicillin in Duodenal Ulcer Healing, Helicobacter pylori Eradication and Duodenal Ulcer Remission in Patients with Acute Duodenal Ulcer. IND #41414

START DATE: Jan 94 EST COMP DATE: Jan 95 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Milton Smith, LTC, MC, Robert Sudduth, MAJ, MC, Dirk Davis, MAJ, MC, Thomas Kepczyk, MAJ, MC, Scot Lewey, MAJ, MC, Steven Hammond, CPT, MC, Laura Farber, RN, Sofia DeAngelis, RN

PERIODIC REVIEW DATE: Dec 93 REVIEW RESULTS: Continue
FUNDING: FACT
GIFTS: Astra/Merck

KEY WORDS: omeprazole, duodenal ulcer, amoxicillin, Helicobacter pylori

OBJECTIVE: To determine if amoxicillin with omeprazole will be safe and effective int he treatment of duodenal ulcer disease.

TECHNICAL APPROACH: Enrollment as per title with randomization to 5 treatment arms, 32 week study, with a maximum of 6 upper GI endoscopies with blood and urine specimens taken and questionnaires given.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: The sponsor never opened the study to enrollment.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-107

Breast and Colon Cancer Agenetic Association Requires Synchronous and Metachronous Screening for both Cancers

START DATE: Jan 94 EST COMP DATE: Jan 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Dennis Ahnen, MD, Milton Smith, LTC, MC, Robert Sudduth, MAJ, MC, Dirk Davis, MAJ, MC, Thomas Kepczyk, MAJ, MC, Laura Farber, RN, Sofia DeAngelis, RN, Daniel Tell, LTC, MC, Jerry Sims, COL, MC, Kevin Rak, MAJ, MC

PERIODIC REVIEW DATE: Feb 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: cancer screening, genetic association

OBJECTIVE: To determine if an association between breast cancer and colon cancer exists.

TECHNICAL APPROACH: Prospective colonoscopic evaluation of all women with a new diagnosis of breast malignancy; prospective screening (mammographic and manual examination) of all women with a new diagnosis of colon cancer; screening (colorectal or breast) for all women identified from our tumor registry with a histologic diagnosis of colon or breast malignancy; evaluation of the chromosome 2, repetitive polymorphism as a marker for synchronous and metachronous breast/colon cancer.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Retrospective review of FAMC records confirms importance of this study. Still awaiting consideration for grant funding. Enrollment on hold for now.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-108

Barrett's Esophagus and Adjuvant Chemotherapy for Breast Cancer. Is There an Association?

START DATE: Jan 94 EST COMP DATE: Jan 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Dennis Ahnen, MD, Milton Smith, LTC, MC, Robert Sudduth, MAJ, MC, Dirk Davis, MAJ, MC, Thomas Kepczyk, MAJ, MC, Laura Farber, RN, Sofia DeAngelis, RN, Daniel Tell, LTC, MC, Jerry Sims, COL, MC

PERIODIC REVIEW DATE: Jan 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: Barrett's esophagus, breast cancer

OBJECTIVE: To determine if an association exists between Barrett's esophagus and treatment of breast cancer exists.

TECHNICAL APPROACH: Prospective endoscopic evaluation of women pre- and post adjuvant chemotherapy for breast cancer for the evolution of Barrett's esophagus; prospective evaluation of prevalence of Barrett's esophagus among women with breast cancer (+/- chemotherapy); prospective, randomized, placebo-controlled trial to evaluate the effectiveness of intercurrent administration of omeprazole to prevent development of Barrett's esophagus among women with breast cancer undergoing adjuvant chemotherapy.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Still awaiting decision on funding re:Women's Health Awards. If 2nd run of awards do not fund this study, we will have to abort. Funding essential for personnel.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-109

Partnership for Quality Living: A Multicenter Study to Develop a National Database from Patients with Ulcerative Colitis

START DATE: Sep 93 EST COMP DATE: Sep 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Milton Smith, LTC, MC, Robert Sudduth, MAJ, MC, Dirk Davis, MAJ, MC, Thomas Kepczyk, MAJ, MC, Scot Lewey, MAJ, MC, Steven Hammond, MAJ, MC, Steve Lawrence, MAJ, MC, Laura Farber, RN

PERIODIC REVIEW DATE: Sep 93 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: Kabi Pharmacia will provide all survey/questionnaires and postage.

KEY WORDS: Crohn's disease, ulcerative colitis

OBJECTIVE: To gather data and collect information needed to develop new and better treatment options and to improve the quality of life for thousands of sufferers nationwide.

TECHNICAL APPROACH: Prognostic questionnaires will be completed by the physicians three times for each participating patient. Subjects will complete quality of life questionnaires three times. Participation Tracking Forms, completed when prescriptions are filled at the pharmacy, will capture information on patient compliance.

PROGRESS:

Number of subjects enrolled to date: 4
Number of subjects enrolled for reporting period: 4
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Four patients entered into national databank. Will need to maintain study to permit continued enrollment.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-110

The Pharmacokinetics of Methylprednisolone in Asthmatic Patients with Acute Bronchospasm

START DATE: Jan 94 EST COMP DATE: Jun 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Peter Ruggiero, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med/All-Imm

ASSOCIATE INVESTIGATORS: P. Dennis Dyer, LTC, MC, Michael O'Connell, MAJ, MC, Matthew Schofield, CPT, MS

PERIODIC REVIEW DATE: Jan 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: bronchospasm, methylprednisolone

OBJECTIVE: To investigate how methylprednisolone is metabolized by asthmatic patients who are acutely ill with significant respiratory compromise.

TECHNICAL APPROACH: Subjects who meet entry criteria will be given one oral dose of the drug. Following ingestion of the drug, serial blood specimens will be obtained which will enable the researchers to determine how quickly the medication is metabolized by the subject's body. At a later date subjects will return for repeat dose and serial blood specimens.

PROGRESS:
Number of subjects enrolled to date: 5
Number of subjects enrolled for reporting period: 5
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Data gathering is progressing.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-111

Parasitic Disease Drug Service - Suramin (Fourneau 309) (Bayer 205) (Germanin) (Monranyl) (Benganyl) (Naphuride) (Antrypol) for Trypanosomiasis and Melarsoprol (Mel B) (Trimelarsan)

START DATE: Jan 94 EST COMP DATE: Mar 94 STATUS: Completed

PRINCIPAL INVESTIGATOR: Wheaton Williams, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Infect Dis

ASSOCIATE INVESTIGATORS: S.M.Harrison, COL, MC, Erin Palestro, RN

PERIODIC REVIEW DATE: Feb 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: CDC provides the IND drugs

KEY WORDS: IND, sleeping sickness

OBJECTIVE: Compassionate treatment of a single subject diagnosed with sleeping sickness. These drugs are standard of care in Africa, but are considered "orphan drugs" in this country.

TECHNICAL APPROACH: Per CDC protocol.

PROGRESS:
Number of subjects enrolled to date: 1
Number of subjects enrolled for reporting period: 1
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None

Summary of prior and current progress: Treatment completed successfully.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-112

One-time use of investigational new drug, transretinoic acid, for the treatment of promyelocytic leukemia

START DATE: Jan 94 EST COMP DATE: Indefinite STATUS: Completed

PRINCIPAL INVESTIGATOR: Patrick Judson, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Hem-Onc

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: Feb REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NCI-IND

KEY WORDS: leukemia, trans retinoic acid

OBJECTIVE: Most probable drug to induce a remission in promyelocytic leukemia after failure of usual agents.

TECHNICAL APPROACH: Per NCI treatment protocol.

PROGRESS:
Number of subjects enrolled to date: 1
Number of subjects enrolled for reporting period: 1
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Patient off study. Patient has been transferred to Wilford Hall for transplant.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-113

Randomized Trial of Nortriptyline for Smoking Cessation

START DATE: Aug 94 EST COMP DATE: Aug 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Michael Weaver, COL, MC

FACILITY/DEPT/SVC: FAMC/Med/Int Med

ASSOCIATE INVESTIGATORS: William Reed, LTC, MC, Anita Huttenhower, PharmD., Jaime Soria, MAJ, AN, FAMC; CPT Richard Keller, AN, AMEDD Student Detachment, FSH, TX (U of WA)

PERIODIC REVIEW DATE: Mar 94 REVIEW RESULTS: Approved
FUNDING: DOD/VA
GIFTS: NA

KEY WORDS: nortriptyline, smoking cessation

OBJECTIVE: Treatment of smokers, both with and without a history of past major depression, with a tricyclic antidepressant, nortriptyline, can reduce tobacco withdrawal symptoms and increase long term cessation rates when combined with a behavioral cessation program.

TECHNICAL APPROACH: Placebo-controlled, parallel group trial with randomization stratified by prior history of depression and by study site.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: No progress. Grant recently approved.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-114A

Effects of Beta-Blockers on Intracellular Cyclic Guanylate Nucleotide Generation in Guinea Pig (Cavia porcellus) Airway Smooth Muscle

START DATE: Jan 94 EST COMP DATE: May 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Vincent Dubravec, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med/All-Imm

ASSOCIATE INVESTIGATORS: Michael O'Connell, MAJ, MC, Paul Schkade, MAJ, MC, Philip Dyer, LTC, MC

PERIODIC REVIEW DATE: Dec 93 REVIEW RESULTS: Approved
FUNDING: FACT
GIFTS: FACT

KEY WORDS: beta blockers, smooth muscle

OBJECTIVE: Airway smooth muscle treated with a beta-blocker will show cyclic GMP levels that will correlate with previously studied cyclic AMP levels (protocol 91/138A) if the control of these two nucleotides are coupled via the beta receptor complex; tissue cGMP levels will not correlate with cAMP responses if these two nucleotide generating systems are not coupled via the beta-receptor complex.

TECHNICAL APPROACH: Tracheal strips will be prepared per experimental design and phase 1 and phase 2 performed.

PROGRESS:

Number of subjects enrolled to date: 20
Number of subjects enrolled for reporting period: 20
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Tissue from 20 euthanatized guinea pigs has been processed, and we are currently in the process of running RIAs. We will then evaluate the data to date.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-115A

Propagation of Trypanosoma Brucei in Rodents

START DATE: Jan 94 EST COMP DATE: May 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Wheaton Williams, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Infec Dis

ASSOCIATE INVESTIGATORS: Shannon Harrison, COL, MC

PERIODIC REVIEW DATE: Jan 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: sleeping sickness

OBJECTIVE: Definitive diagnosis of African Sleeping Sickness by identification of parasite in blood smears of the patient or in the blood smears of inoculated rodents. More sensitive assessment of disease progression than cytological examination of patient CSF.

TECHNICAL APPROACH: Rats will be inoculated with either the patient's blood or spinal fluid. Rodent blood will be examined periodically for 60 days. Harvested blood will be collected in EDTA tubes mixed with preservative and frozen in liquid nitrogen.

PROGRESS:

Number of subjects enrolled to date: 6
Number of subjects enrolled for reporting period: 6
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Study complete. Rat blood smears collected. If patient develops recurrent symptoms, may need to re-inoculate rodents again in future.

PUBLICATIONS: None.

PRESENTATIONS: Clinical vignette at Colorado American College of Physicians meeting.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-116

Search for the Precursor Cell of Extramammary Paget's Disease in Autopsy Specimens of Axilla, Nipple and Groin Using Immunoperoxidase Markers

START DATE: Feb 94 EST COMP DATE: Feb 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Thomas McGovern, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med/Derm

ASSOCIATE INVESTIGATORS: James Fitzpatrick, COL, MC, Stephen Groo, MAJ, MC, Sal Fong, MD

PERIODIC REVIEW DATE: Mar 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: Paget's disease, immunoperoxidase markers

OBJECTIVE: Using skin samples from the nipple lines of autopsy specimens, we will stain them with hematoxylin and eosin (H&E) and immunoperoxidase stains which characteristically decorate Paget cells: CEA, EMA and low molecular weight cytokeratins to locate "Tokaer's clear cells' in tissue free of malignancy. Such an immunoperoxidase profile would strongly suggest that these are the progenitor cells of MPD (without underlying ductal carcinoma) and EMPD.

TECHNICAL APPROACH: Biopsy evaluation of 100 autopsy subjects as per objective.

PROGRESS:

Number of subjects enrolled to date: 4
Number of subjects enrolled for reporting period: 4
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Biopsies harvested. No immunostaining done yet. Waiting for more autopsy material.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-117

Comparison of Single-Photon Emission Computed Tomography (SPECT) Analysis of Cerebral Blood Flow with Brain Magnetic Resonance Imaging and Neuropsychological Testing in the Evaluation of Patients with Systemic Lupus Erythematosus with and without Neuropsychiatric Manifestations - A Pilot Study

START DATE: Apr 94 EST COMP DATE: Oct 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Sterling West, COL, MC

FACILITY/DEPT/SVC: FAMC/Med/Rheum

ASSOCIATE INVESTIGATORS: Albert Lambert, MAJ, MC, Kevin Rak, MAJ, MC, Alan Erickson, CPT, MC, Elizabeth Kozora, PhD, NJH

PERIODIC REVIEW DATE: Apr 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: lupus, blood flow

OBJECTIVE: To determine if HM-PAO brain SPECT is better modality than MRI in comparison with neuropsychiatric testing in evaluating SLE patients with and without CNS disease.

TECHNICAL APPROACH: SPECT will be administered as non-standard of care element of this protocol. Data analysis after 20 subjects are studied.

PROGRESS:
Number of subjects enrolled to date: 2
Number of subjects enrolled for reporting period: 2
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: No significant data yet.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-118

Immunoregulation and Pathogenesis of Symptomatic, Primary HIV-1 Infection

START DATE: Apr 94 EST COMP DATE: Apr 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Wheaton Williams, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Infect Dis

ASSOCIATE INVESTIGATORS: Wheaton Williams, MAJ, MC

PERIODIC REVIEW DATE: Apr 94 REVIEW RESULTS: Continue
FUNDING: HMJF
GIFTS: NA

KEY WORDS: HIV, immunoregulation, pathogenesis

OBJECTIVE: To better understand how the HIV virus changes its form (genetic makeup) as it divides in a patient over time.

TECHNICAL APPROACH: Study of blood and body fluids using special laboratory tests and to establish a bank of properly stored peripheral blood mononuclear cells (PBMC), sera, and other body fluids from this group of patients for potential use in future studies.

PROGRESS:
Number of subjects enrolled to date: 1
Number of subjects enrolled for reporting period: 1
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: One patient enrolled at FAMC but terminated early secondary to discharge from service.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-119A

Evaluation of Different Suture Patterns and Angioplasty Balloons on Vein Graft Anastomoses in the Domestic Pig (Sus scrofa)

START DATE: Apr 94 EST COMP DATE: Jul 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Talley Culclasure, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med/Card

ASSOCIATE INVESTIGATORS: Mark Dorogy, MAJ, MC

PERIODIC REVIEW DATE: Mar 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: anastomoses, suture training, angioplasty

OBJECTIVE: To determine the safety and limitations of angioplasty on vein graft anastomoses in early peri-operative period.

TECHNICAL APPROACH: Vein grafts harvested from the animal will be sutured into place on the carotid artery in an end to side fashion (two touchdowns per vein graft). Two suture styles will be used to replicate the techniques currently sued in vascular surgery: 1) running suture and 2) interrupted suture. After completion of the surgical procedure, the vein-graft anastomosis lumen size will be determined by intravascular ultrasound catheters. Appropriate sized balloon catheters will be introduced through the vein graft and balloon angioplasty will be performed. These anastomoses will be visually inspected and then harvested for microscopic evaluation.

PROGRESS:

Number of subjects enrolled to date: 3
Number of subjects enrolled for reporting period: 3
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: On schedule.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-120

Urgent Revascularization in Unstable Angina

START DATE: NA EST COMP DATE: NA STATUS: Withdrawn

PRINCIPAL INVESTIGATOR: William Highfill, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Card

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: NA REVIEW RESULTS: Withdrawn
FUNDING: NA
GIFTS: NA

KEY WORDS: NA

OBJECTIVE: NA

TECHNICAL APPROACH: NA

PROGRESS:
Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Withdrawn prior to IRC review due to unresolved issues.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-121

The Effect of Estrogen and Ultraviolet Light on the Translocation of Ro/SSA within Human Keratinocytes

START DATE: May 94 EST COMP DATE: May 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Scott Bennion, COL, MC

FACILITY/DEPT/SVC: FAMC/Clin Invest/Cell Phys

ASSOCIATE INVESTIGATORS: Kathleen David-Bajar, MAJ, MC, Ronald Jackson, PhD

PERIODIC REVIEW DATE: May 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: estrogen, ultraviolet light, keratinocytes

OBJECTIVE: To determine whether estrogens or UVL, singly or in combination, have an effect on the translocation of Ro/SSA from the cell cytoplasm to the cell surface of human keratinocytes. To examine this phenomenon at the ultrastructural level utilizing immunogold labelling to determine the exact location of Ro/SSA within the cell cytoplasm and the cell surface.

TECHNICAL APPROACH: No human subjects will be involved in this study. Keratinocytes are derived from neonatal foreskins which are normally discarded from the Newborn Nursery. The human sera utilized in this study is banked from previous protocols or will be taken from blood drawn for routine laboratory studies in clinical workups of patients. Laboratory methods used in this project are currently being used in the Cell Physiology Service, DCI.

PROGRESS:

Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: No progress to date. Work on immunoeletron microscopy utilizing immunogold staining is progressing. Once the technique is perfected the study will be started.

PUBLICATIONS: ?

PRESENTATIONS: ?

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-122A

Photosensitive Lupus Erythematosus: A Women's Disease - Use of Transgenic Mice to Distinguish Mechanisms of Discoid and Subacute Cutaneous Lupus

START DATE: Jul 94 EST COMP DATE: Jun 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Kathleen David-Bajar, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Derm

ASSOCIATE INVESTIGATORS: Scott Bennion, COL, MC, Ronald Jackson, Ph.D., Martin Johnson, CAPT, USAF, MC

PERIODIC REVIEW DATE: May 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: lupus erythematosus, antibodies

OBJECTIVE: To define autoimmune keratinocyte destruction, the central component of photosensitive lupus, in women, by defining the disease components in an animal model.

TECHNICAL APPROACH: Produce animal models that mimic human skin disease associated with lupus erythematosus.

PROGRESS:
Number of subjects enrolled to date: None.
Number of subjects enrolled for reporting period: None.
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Transgenic ICAM-1+ male mice and FVB female mice have been received. Attempts are being made to establish a breeding colony.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-123

A Pilot Study of a New Esophageal Cytology Device (Brandt Cytology Balloon) to Evaluate Patients with Barrett's Esophagus for Metaplastic Dysplasia and Malignancy

START DATE: NA EST COMP DATE: NA STATUS: Withdrawn

PRINCIPAL INVESTIGATOR: Scot Lewey, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: NA REVIEW RESULTS: Withdrawn
FUNDING: NA
GIFTS: NA

KEY WORDS: NA

OBJECTIVE: NA

TECHNICAL APPROACH: NA

PROGRESS:

Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Withdrawn prior to IRC review due to unresolved impact issues.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-124

Evaluation of the Clinical and Cost Effectiveness of Therapy with Clarithromycin Plus Omeprazole Compared to Omeprazole or Ranitidine for the Treatment of Patients with Duodenal Ulcer and Helicobacter Pylori Infection.(IND 31,703)

START DATE: Jul 94 EST COMP DATE: Jan 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Milton Smith, LTC, MC, Dirk Davis, MAJ, MC, Thomas Kepczyk, MAJ, MC, Scot Lewey, MAJ, MC, Steven Hammond, MAJ,, MC, Brian Long, LPN

PERIODIC REVIEW DATE: Jun 94 REVIEW RESULTS: Approved
FUNDING: FACT
GIFTS: Abbott

KEY WORDS: ulcer, Helicobacter pylori, clarithromycin, omeprazole, ranitidine

OBJECTIVE: To determined if clarithromycin, an antibiotic, when given with omeprazole, an anti-ulcer medication, will have a beneficial and cost effective outcome for ulcer disease.

TECHNICAL APPROACH: Ten patients randomized, double-blind, to receive either clarithromycin and omeprazole; omeprazole or ranitidine alone, for 28 days.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Will begin enrollment end of Sept. Study delay due to regulatory review.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-125

A Double-Blinded, Randomized Trial Comparing Zidovudine (ZDV) vs. ZDV + Didanosine (ddI) vs. ZDV + ddI + Nevirapine (NVP) in Asymptomatic Patients on ZDV Monotherapy Who Develop a Mutation at Codon 215 of HIV Reverse Transcriptase in Serum/Plasma Viral RNA. (ACTG Protocol #224, Version 2.0) IND#42,003

START DATE: Jul 94 EST COMP DATE: Jul 99 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Wheaton Williams, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Inf Dis

ASSOCIATE INVESTIGATORS: Donald Skillman, LTC, MC

PERIODIC REVIEW DATE: Jul 94 REVIEW RESULTS: Approved
FUNDING: MMCARR
GIFTS: ACTG

KEY WORDS: HIV, RNA, ZDV, ddI, NVP

OBJECTIVE: Prove that a specific change (mutation) in virus appears in the blood before the amount of virus in the blood increases and T4 cells decrease; determine whether adding other anti-HIV medications (Didanosine, Nevirapine) changes the amount of HIV in the blood of those patients who develop the mutant virus; provide information concerning the safety and efficacy of the combination of zidovudine, Didanosine (ddI) and Nevirapine (NVP).

TECHNICAL APPROACH: Per title, objective and ACTG protocol.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: No progress.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-126

An Open-Label, Randomized Trial of Four Treatment Regimens for Patients with Disseminated Mycobacterium avium Complex Disease and Acquired Immunodeficiency Syndrome (AIDS). (CPCRA 027, IND#43,458)

START DATE: Jul 94 EST COMP DATE: Jul 98 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Wheaton Wiilliams, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Med/Inf Dis

ASSOCIATE INVESTIGATORS: Donald Skillman, LTC, MC

PERIODIC REVIEW DATE: Jul 94 REVIEW RESULTS: Approved
FUNDING: CPCRA
GIFTS: IND drugs

KEY WORDS: AIDS, Mycobacterium avium, clarithromycin, rifabutin, ethambutol, clofazimine

OBJECTIVE: To determine whether there is a difference in treating disseminated Mycobacterium avium infection in AIDS subjects with clarithromycin 500 mg twice a day or clarithromycin 1,000 mg twice a day and if there is a difference in treating with rifabutin or clofazimine.

TECHNICAL APPROACH: As per title, objective, and NIH/CPCRA protocol. Ten subjects to be enrolled at FAMC over the next 2 years with minimum patient followup of 1.5 years.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: No progress.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-127

A Multicenter, Double-Blind, Randomized Study to Evaluate the Effects of Omeprazole 20 mg B.I.D. Coadministered with Amoxicillin 1 g. T.I.D. in Helicobacter pylori Eradication in Patients with Inactive Duodenal Ulcer. (MK-764 #036 A/M 5/3/94, IND#41,414)

START DATE: Sep 94 EST COMP DATE: Sep 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Peter McNally, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Gastro

ASSOCIATE INVESTIGATORS: Milton Smith, LTC, MC, Dirk Davis, MAJ, MC, Thomas Kepczyk, MAJ, MC, Scot Lewey, MAJ, MC, Steven Hammond, MAJ,, MC, Brian Long, LPN

PERIODIC REVIEW DATE: Jul 94 REVIEW RESULTS: Approved
FUNDING: FACT
GIFTS: Astra/Merck

KEY WORDS: ulcer, omeprazole, amoxicillin, Helicobacter pylori

OBJECTIVE: To determine the safety and efficacy of the drug combination in the treatment of duodenal ulcer disease.

TECHNICAL APPROACH: At FAMC 5-15 subjects will be enrolled as per title.

PROGRESS:

Number of subjects enrolled to date: 3
Number of subjects enrolled for reporting period: 3
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Study initiation was delayed due to internal MSD re-alignment. Anticipate 10-20 patients for enrollment this year.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-128

Evaluation of In Vitro Allergenic Cross-Reactivity Among Trees

START DATE: Jun 94 EST COMP DATE: Jul 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Clifford Friesen, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/All-Imm

ASSOCIATE INVESTIGATORS: Robert Ledoux, BS, DAC, Paul Schkade, MAJ, MC

PERIODIC REVIEW DATE: Jun 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: tree pollen, cross-allergenicity

OBJECTIVE: To investigate the degree of in vitro cross-reactivity of taxonomically related trees.

TECHNICAL APPROACH: ELISA assay will be performed on the sera of patients who have strongly reactive skin tests to trees. ELISA inhibition assays will be used to generate inhibition curves among various tree pollens. From these curves the degree of cross-reactivity will be determined. In the second part, molecular weights of cross-reacting tree pollen proteins will be determined by SDS-PAGE electrophoresis, followed by IgE immunoblotting techniques, using the allergic sera identified above. IgE immunoblot inhibitions will give strong evidence of cross reactivity among particular tree pollens.

PROGRESS:

Number of subjects enrolled to date: 17
Number of subjects enrolled for reporting period: 17
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Screening sera and pooled sera and perfecting laboratory procedures.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-129

The Effects of Region-Specific Resistance Exercises on Bone Mass in Premenopausal Military Women

START DATE: Oct 94 EST COMP DATE: Oct 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Michael McDermott, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Endo

ASSOCIATE INVESTIGATORS: Reed Christensen, MAJ, MC, Albert Lambert, MAJ, MC

PERIODIC REVIEW DATE: Sep 94 REVIEW RESULTS: Approved
FUNDING: DWHRP
GIFTS: NA

KEY WORDS: bone mass, exercise, women

OBJECTIVE: Investigate the effects of two types of exercise, aerobic and resistance, on the calcium content of premenopausal women's bones.

TECHNICAL APPROACH: Prospective, randomized study of 60 healthy premenopausal women. Physical activity for at least 30 minutes a session, 3 days a week for a period of 1 year with 1000 mg calcium intake.

PROGRESS:

Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Study recently approved, awaiting funding from Defense Women's Health Research Program.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-130

Assessment of Dietary Calcium Intake, Physical Activity and Habits Affecting Skeletal Health Among Premenopausal Military Women

START DATE: Sep 94 EST COMP DATE: Sep 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Michael McDermott, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Endo

ASSOCIATE INVESTIGATORS: Reed Christensen, MAJ, MC, Albert Lambert, MAJ, MC, Donna Dolan, CPT, MSC

PERIODIC REVIEW DATE: Sep 94 REVIEW RESULTS: Approved
FUNDING: DWHRP
GIFTS: NA

KEY WORDS: calcium, exercise, bone mass

OBJECTIVE: Investigate the effects of various life-style factors such as calcium intake, exercise, smoking and drinking alcohol and caffeine on female bone density.

TECHNICAL APPROACH: Questionnaires to 1000 active duty premenopausal women regarding daily and weekly intakes of specific high calcium foods and calcium supplements, performance of specific aerobic and resistive exercises, and daily quantity of smoking, consumption of alcohol and caffeine containing beverages. Subset of 100 will have blood drawn for CBC and measurement of serum calcium, phosphorus, chloride, alkaline phosphatase, PTH and TSH and will have their bone density measured in the lumbar spine, femoral neck, mid-radius and distal radius by dual energy x-ray absorptiometry.

PROGRESS:

Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Recently approved study, awaiting funding from Defense Women's Health Research Program.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-131

The Effects of Previous Thyroid Hormone Suppression Therapy on the Peak TSH Level Achieved During Whole Body ^{131}I Scanning for Thyroid Cancer

START DATE: Sep 94 EST COMP DATE: Sep 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Michael McDermott, COL, MC

FACILITY/DEPT/SVC: FAMC/Med/Endo

ASSOCIATE INVESTIGATORS: Reed Christensen, MAJ, MC

PERIODIC REVIEW DATE: Sep 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: thyroid cancer, radioiodine

OBJECTIVE: To determine if thyroid cancer patients who have been on long-term levothyroxine suppression therapy are more likely to have a scintigraphically inadequate elevation of the serum TSH level after a standard 6 week interval of levothyroxine abstinence.

TECHNICAL APPROACH: Prospective study collecting and analyzing data which is normally ordered for clinical reasons in patients who are undergoing ^{131}I whole body scanning for thyroid cancer followup.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: None. Study recently approved.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-132

Effect of Shiitake Mushrooms on Blood Eosinophil Count: A Pilot Study.

START DATE: Sep 94 EST COMP DATE: Mar 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Vincent Dubravec, CPT, MC

FACILITY/DEPT/SVC: FAMC/Med/All-Imm

ASSOCIATE INVESTIGATORS: Paul Schkade, MAJ, MC, P.Dennis Dyer, LTC, MC

PERIODIC REVIEW DATE: Oct 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: eosinophilia, mushroom ingestion

OBJECTIVE: To confirm increase in eosinophils from shiitake mushroom powder and to search for an underlying cause.

TECHNICAL APPROACH: Five to ten subjects will take 4 grams of shiitake mushroom powder daily for up to 8 weeks and will report an symptoms that develop. Subjects will be monitored for eosinophil count at baseline and every two weeks.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: None. Study recently approved.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR SOUTHWEST ONCOLOGY GROUP PROTOCOLS

90/126 SWOG 8710	91/102 SWOG 8894	93/107 SWOG 9030
90/129 SWOG 8814	91/103 SWOG 8906	93/109 SWOG 9148
90/138 SWOG 8520	91/104 SWOG 8925	93/116 SWOG 9008
90/140 SWOG 8692	91/118 SWOG 9013	93/117 SWOG 9119
90/141 SWOG 8711	91/119 SWOG 9038	93/119 SWOG 9216
90/142 SWOG 8736	91/133 SWOG 9111	93/122 SWOG 9003
90/144 SWOG 8794	91/150 SWOG 9007	93/123 SWOG 9031
90/146 SWOG 8809	91/151 SWOG 9108	93/124 SWOG 9032
90/147 SWOG 8819	92/101 SWOG 8913	93/125 SWOG 9133
90/158 SWOG 8851	92/102 SWOG 8956	93/132 SWOG 9034
90/159 SWOG 8892	92/122 SWOG 9061	93/133 SWOG 9104
90/164 SWOG 8952	92/143 SWOG 9035	93/134 SWOG 9143
90/176 SWOG 8994		

START DATE: 1980 EST COMP DATE: Indefinite STATUS: On Hold.

PRINCIPAL INVESTIGATOR: Daniel Tell, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Hem-Onc

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: 4 Jan 94 REVIEW RESULTS: On Hold.
FUNDING: NA
GIFTS: NA

KEY WORDS: cancer

OBJECTIVE: Cancer treatment.

TECHNICAL APPROACH: Per NCI protocol.

PROGRESS:
Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor: NA

Summary of prior and current progress: No new subjects enrolled since the elimination of the position of oncologist data manager at FAMC. The PI requested the protocol be put on hold. The IRC approved the "on hold" status for a period not to exceed one year. No new patients may be enrolled on any of the studies without IRC approval for that patient. Currently no one is on active treatment on SWOG protocols.

PUBLICATIONS: None. PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR SOUTHWEST ONCOLOGY GROUP PROTOCOLS

90/143 SWOG 8793	90/175 SWOG 8931	91/140 SWOG 9040
90/150 SWOG 8905	91/103 SWOG 8906	91/141 SWOG 9009
90/154 SWOG 8326	91/109 SWOG 9037	91/147 SWOG 8730
90/155 SWOG 8810	91/129 SWOG 9046	91/148 SWOG 8911
90/160 SWOG 8897	91/139 SWOG 9045	91/149 SWOG 8936
		92/103 SWOG 9016
		93/110 SWOG 9215
		93/118 SWOG 9134

START DATE: 1980 EST COMP DATE: Indefinite STATUS: **Terminated.**

PRINCIPAL INVESTIGATOR: Daniel Tell, LTC, MC

FACILITY/DEPT/SVC: FAMC/Med/Hem-Onc

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: 4 Jan 94 REVIEW RESULTS: Terminated.
FUNDING: NA
GIFTS: NA

KEY WORDS: cancer

OBJECTIVE: Cancer treatment.

TECHNICAL APPROACH: Per NCI protocol.

PROGRESS:
Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor: NA

Summary of prior and current progress: These protocol were closed.

Detail Summary Sheet

(1) Date: 5 Apr 94 (2) Protocol #: 87/204 (3) Status: Terminated

(4) Title: Mechanism Based Treatments of Phantom Limb Pain

(5) Start Date: 1987 (6) Est Compl Date: 1992

(7) Principal Investigator: Richard A. Sherman, LTC, MS (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators

Timothy Young, MD, Augusta, VAMC
Robert Rodinelli, MD, Denver, VAMC

(11) Key Words:

phantom limb pain
treatments

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: APRIL b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 104
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate the effectiveness of treatments for burning phantom limb pain.

(16) Technical Approach: We will treat four groups of ten amputees each with the same six interventions. The amputees will be grouped by the description of their phantom pain. We will work with those describing their phantom pain as (1) only burning, (2) only cramping, (3) mixed cramping and burning, and (4) shooting / stabbing / shocking. Before treatment begins, there will be a three week baseline in which each amputee will be interviewed and stump muscle tension and heat outflow patterns will be recorded. Each amputee will receive each treatment for one month unless side effects force withdrawal. Treatment months will alternate with three week "washout" periods to permit phantom pain to return to baseline. The treatments will be: (1) topical application of nitroglycerine for mainly venous-side vasodilatative effects, (2) trental to reduce blood viscosity so more blood can reach tissues in the stump having compromised vascular beds, (3) Nifedipine as a Calcium channel blocker for its known peripheral vasodilatative effects, (4) Cyclobenzaprine for its ability to reduce spasms of local origin without interfering with muscle function, (5) muscle tension recognition and relaxation training for its proven ability to reduce microspasms and

tension related to intensification of phantom pain, and (6) body surface temperature recognition and control training for its ability to help-people control vasodilation of peripheral vessels while under stress. Subjects will be recorded the same way they were during the baseline at each session to permit objective verification of physiological changes. They will come to the clinic every other week during treatments. At the end of the last treatment, there will be another three week baseline. Following the final baseline, the treatment which proved most effective, if any, will be continued for one year. Subjects will be recorded at monthly intervals. If no treatments are effective, subjects will still be followed for one year but will be recorded at six and twelve months. Patients with burning pain who fail standard treatment will receive pulsing electromagnetic field therapy.

(17) Progress: Virtually all patients have buring or cramping phantom pain were cured or helpd substantially to the point where no more medication is required. Patients with shocking pain were two exceptions, were either helped marginally or not at all. One of the exceptions found a local herbal medicine that stops the pain which we are investigation with the pharmacy's help. The other learned to avoid permitting the pain to begin by controlling limb temperature.
FY 94: PI PCS'd to Madigan AMC.

Publications:

Sherman R, Ernst J, Barja R, Bruno G: Phantom pain: A lesson in the necessity for carrying out careful clinical research in chronic pain problems. Rehabilitation Research and Development, 25(2): vii-x, 1988. (Editorial)

Sherman R, Barja R: Treatment of post-amputation and phantom limb pain. In (K. Foley and R. Payne, eds.) Current therapy of pain. B.C. Decker, Publisher, Ontario, 1988. (Chapter)

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Biofeedback and Self-Regulation, 13(1):55, 1988. (Abstract)

Sherman R, Arena JG, Bruno GM, Smith JD: Precursor relationships between stress, physical activity, meterorological factors, and phantom limb pain: Results of six months of pain logs. Proceedings of the Joint meeting of the Canadian and American Pain Societies, Toronto Canada, November, 1988 (Abstract).

Sherman R: Phantom limb and stump pain. chapter in (R. Portenoy, ed) Neurologic Clinics of North America. W.B. Saunders Co., Publisher, 1989, (Chapter).

Sherman R, Sherman C, Grana A: Occurrence of acture muscle contractions in the residual limbs of amputees preceding acute episodes of phantom limb pain. Biofeedback and Self-Regulations, 1989 (Abstract).

Arena J, Sherman R, Bruno G: The relationship between humidity level, temperature, and phantom limb pain: Preliminary Analysis. Proceedings of the annual meeting of the Association for Applied Psychophysiology, 1989 (Abstract).

Sherman RA, Griffin VD, Evans CB, Grana AS: Temporal relationships between changes in phantom limb pain intensity and changes in surface electromyogram of the residual limb. Int. J. Psychophysiology, 13:71-77, 1992.

Presentations:

Sherman R: Mechanisms of phantom pain: new findings: Presented: Proceedings of the 21 Annual meeting of the Association for Applied Psychophysiology, Washington, D.C., 1990.

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 87/207 (3) Status: Completed

(4) Title: Determination of Mechanisms of Phantom Limb Pain: Phase 2

(5) Start Date: 1987 (6) Est Compl Date:

(7) Principal Investigator: Richard A. Sherman, LTC, MS (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators

(11) Key Words: phantom limb pain

Jeffrey Ginther, MAJ, MC
JD Griffin, RN

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 45
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To use MRI, nerve recording, and other techniques to monitor veteran and active duty amputees who report shocking, shooting, and stabbing descriptors of phantom limb pain while they are experiencing various intensities of pain in order to ascertain the physiological changes which are related to changes in pain intensity.

(16) Technical Approach: We will carry out the pilot for a full proposal in which we would record groups of twenty active duty or veteran amputees four times. In the pilot, only two amputees from each group will participate. Two of the recordings will be at one particular pain intensity while the other two will be at two different intensities. This will permit factoring changes due to time from those due to changes in pain intensity. Each subject will be recorded at about weekly intervals but the exact timing will have to depend on when their pain intensity changes. The groups will consist of two amputees with (1) only stabbing phantom pain, (2) only shooting phantom pain, (3) only shocking phantom-pain, (4) a combination of all three (which is common), and (5) no phantom pain. The fifth group of amputees without phantom pain is necessary to further evaluate changes which occur in the normal stump over time so we can differentiate them from abnormal changes. We know from our experience in Phase I of this study that twenty is the minimum number of amputees we can have in a group due to normal physiological variability and in variability in reporting pain intensity. However, two per group will give us an idea of whether the following techniques are likely to show any differences at all. We propose to use MRI to record overall stump anatomy, plethysmography to record swelling and internal stump pressure, and signals from the neuroma to record responses to mechanical

and other stimuli. Because of its invasive nature, we will carry out only one nerve signal study from the stump. For subjects who report phantom pain, we will perform the test on a day when they report the maximum phantom pain they usually experience. We will compare the results of this recording with those from pain free amputees. Due to its cost, we will do MRI recordings of only one subject per pilot group. Two MRI's will be done for each pilot subject. One will be while the subject is as pain free as they get and the other will be while they are experiencing the most pain they generally expect.

(17) Progress: Twenty amputees experiencing numerous acute episodes of cramping phantom pain had the surface muscle tension in their residual limbs recorded. They pressed a button during episodes of phantom pain. Temporal relationships between initiation of episodes and spasms in the limb were established. Spasms preceed start of pain by more than reaction time so causes the phantom pain.

Publications:

Sherman R, Sherman C, Grana A: Occurrence of acute muscle contractions in the residual limbs of amputees preceeding acute episodes of phantom limb pain. Biofeedback & Self-Regulation 14(2):169, 1989.

Sherman R, Bruno G: Concurrent variation of burning phantom limb and stump pain with near surface blood flow in the stump. Orthopedics, 10:1395-1402, 1987.

Sherman R, Sherman C, Bruno G: Psychological factors influencing chronic phantom limb pain: An analysis of the literature. Pain, 28:285-295, 1987.

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Biofeedback and Self-Regulation, 1988, (Abstract).

Sherman RA, Griffin VD, Evans CB, Grana AS: Temporal relationships between changes in phantom limb pain intensity and changes in surface electromyogram of the residual limb. Int. J. Psychophysiology, 13:71-77, 1992.

Sherman RA: Phantom limb pain: Mehcnaisms, incidence, and treatment. Critical Review in Physical and Rehabiliation Medicine, 41:(1,2)1-26, 1992.

Presentations:

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Presented at the 19th Annual meeting of the Society for Applied Psychophysiology in Colorado Springs, CO, March 1988.

Detail Summary Sheet

(1) Date: 3 May 94 (2) Protocol WU#: 88/215 (3) Status: Terminated

(4) Title: Environmental/Temporal Relationships Between Headache and Muscle Tension

(5) Start Date: 1988 (6) Est Compl Date: 1994

(7) Principal Investigator:
Richard A. Sherman, LTC, MS

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators
Cecile Evans, BA COL, MC
Carson Henderson, MSW, Psy.D.
Crystal Sherman, MS
Ellynore Cucinell, COL, MC

(11) Key Words:
headache
muscle tension
environmental recording

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 6
d. Total Number of Subjects Enrolled to Date: 38
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine relationships between motion, muscle tension in the frontal and trapezius muscles, and onset and intensity of headaches among subjects recorded in their normal environments.

(16) Technical Approach: Subjects wear a small EMG and motion recorder during all working hours for one week. They keep an hourly log of types and activity and pain intensity while wearing the recorder.

(17) Progress: Data from 5 males and 5 females (ages 22-67) having tension (5), migraine (3), or mixed (2) headaches participating in the study were analyzed. In each case, the wearable device recorded two channels of EMG from the left and right trapezius muscles, movement, and button presses indicating pain intensity. Subjects wore it all day in their normal environments for three to five days. In two subjects (one tension headache and one migraine), trapezius EMG increased before pain increased. In a third subject (tension headache), EMG was elevated during high pain. In a fourth subject (mixed headache), EMG was lower during pain free recordings than during headaches. In a fifth subject (tension headache), EMG decreased after pain increased. There was no relationship between EMG and pain intensity in the remaining subjects (two tension headaches, two migraine headaches, and one mixed). Thus,

there may be a small sub-set of people who do, in fact, have muscle tension components of their headaches. This is the first time evidence has actually been recorded to support this well accepted but theoretical relationship. All previous, in-laboratory, studies have failed to fine any support for the relationship. FY94: No progress since FY93 APR. PI PCS'd to Madigan AMC.

Publications: Sherman RA, Evans CB, Henderson CY, Sherman CJ, Griffin V, and Arena JG: Continuous environmental recordings of relationships between trapezius EMG, movement, activity, and headache pain intensity. Biofeedback and Self-Regulation, in press, 1992.

Presentations: Sherman RA, Evans CB, Henderson CY, Sherman CJ, Griffin V, and Arena JG: Continuous environmental recordings of relationships between trapezius EMG, movement, activity, and headache pain intensity Presented Annual Meeting of the Association for Applied Psychophysiology, Colorado Springs, 1992.

Detail Summy Sheet

(1) Date: 1 Mar 94 (2) Protocol #: 89/203 (3) Status: Terminated

(4) Title: Rates of Occurrence of Simultaneous and Independent Low Back Pain and Headache Among Patients with and without Chronic Pain

(5)Start Date: 1989 (6) Est Compl Date: 1993

(7) Principal Investigator: Richard A. Sherman, LTC, MS (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators: John G. Arena, Ph.D. Jeffrey R. Ginther, MAJ, MC Melissa Damiano, M.S.

(11) Key Words: low back pain tension headache incidence

(11) Latest IRC Review: MARCH Review Results: Ongoing
Number of Subjects Enrolled During Reporting Period: 0
Total Number of Subjects Enrolled to Date: 95

(12) Study Objective: To determine the temporal relationships between the above pain problems among subjects with and without chronic pain.

(13) Technical Approach: Survey deers eligible people with and without pain while they are waiting for appointment at FAMC.

(14) Progress: No results due to lack of staff.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 89/207 (3) Status: Completed

(4) Title: Etiology and Progression of Acute Muscle Tension Related Low Back Pain Occurring During Sustained Activity Including Combat Training Exercises

(5) Start Date: Oct 1989 (6) Est Compl Date:

(7) Principal Investigator:
Kent Karstetter, MAJ, MC

(8) Facility: FAMC
& Reynolds ACH, Ft. Sill, OK

(9) Dept/Svc: SURG/Orthopedics

(10) Associate Investigators:
David Hahn, LTC, MC
Jeffrey R. Ginther, MAJ, MC
John G. Arena, Ph.D.
(VA, Augusta, GA)
Richard A. Sherman, LTC, MS

(11) Key Words:
low back pain
EMG

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:__ MAY____b. Review Results:Ongoing_
c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____131_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Determine the etiology and progression of acute muscle tension related low back pain occurring during sustained activity including combat training exercises.

(16) Technical Approach: Use ambulatory recorders to make second by second records of bilateral surface paraspinal EMG and back movement as well as hourly back pain and fatigue rating entries for 20 hours per day while subjects function in their normal environment.

(17) Progress: Temporal relationships between (a) headache and trapezius muscle contraction patterns and (b) low back pain and paraspinal muscle contraction patterns are being established. A subgroup of subjects show clear, consistent relationships.
FY94: Request change of FAMC PI to Kent Karstetter, MAJ, MC, with Richard A. Sherman, LTC, MS, as Program Director for all sites effective 5 Aug 94. No progress reported. Project will end on 30 Sep 94.

CONTINUATION SHEET, FY 94, ANNUAL PROGRESS REPORT Protocol # 89/207

Publications:

Sherman R, Arena J, Searle J, and Ginther J: Development of an ambulatory recorder for evaluation of muscle tension related low back pain and fatigue in soldiers' normal environments. Military Medicine. 156:245-248, 1991.

Sherman R, Sherman C: Physiological parameters that change when pain changes: Approaches to unraveling the "cause-or-reaction" quandary. Bulletin of the American Pain Society. 1(4):11-15, 1991.

Sherman R, Varnado S, Caminar S, Arena J: Changes in paraspinal muscle tension as predictors of changes in low back pain. Proceedings of the 1991 annual meeting of the American Pain Society p. 64, 1991. (Abstract)

Sherman R, Evans C, Henderson C, Griffin V, Sherman C, Arena J: Continuous environmental recordings of relationships between Trapezius EMG and headache pain intensity. Biofeedback and Self-Regulation, 17:338, 1992 (Abstract)

Sherman R, Griffin V, Evans C, Grana A: Temporal relationships between changes in phantom limb pain intensity and changes in surface electromyogram of the residual limb. Int. J. of Psychophysiology 13:71-77,1992.

Evans C, Sherman R: Does biofeedback for headache and mechanical low back pain change relationships between muscle tension and pain in the normal environment? Biofeedback and Self-Regulation, accepted for publication 1992. (Abstract)

Sherman R, Evans C, and Arena J: Environmental - temporal relationships between pain and muscle tension. Chapter in Biofeedback: Theory and Practice, edited by M Shtark and T Sokhadze, Nauka publishers, 1992. (Chapter)

Presentations: None

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 89/210 (3) Status: Completed

(4) Title: Use of Body Surface Heat Patterns for Predicting and Evaluating Acute Lower Extremity Pain Among Soldiers

(5) Start Date: Oct 89 (6) Est Compl Date: Sep 94

(7) Principal Investigator:
Kent Karstetter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Orthopedic Svc

(10) Associate Investigators:
Allyn Woerman, LTC, PT
Ft. Sill, OK
Richard Sherman, LTC, MS

(11) Key Words:
thermography
lower extremity pain
surface temperature

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1445
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide immediate, on-site diagnosis of stress fractures in the lower extremities of active duty soldiers using a comparison of high technology videothermography and bone scan with filed viable contact thermography and surface temperature probes.

(16) Technical Approach: Phase I) Use videothermography and standard physical evaluations to establish baselines for trainees initially entering service at Ft. Sill, OK. Repeat thermograms will be performed on all trainees reporting to the troop medical clinic for treatment of pain in their knees, lower legs, and feet. Thermography will be performed on a matched group of trainees who come in to the clinic for other problems. This will permit differentiation of changes which occur among most trainees from pathological changes.
Phase II) Compare videothermograms, contact thermograms, bone scans and other recordings of 100 trainees and 100 relatively senior soldiers suspected of having stress fractures with similar evaluations of matched controls to establish the efficacy of low technology contact thermography for evaluation of stress fractures.

(17) Progress: Phase I: Over half of the trainees had asymetrical patterns during their pro-training baseline. The majority of those develped lower limb pain. Ways to predict which trainees will develop severe lower limb pain will based on baseline thermograms being developed. Phase II: Contact thermography has been shown to be useless for evaluating lower limb pain in our population because the device can not be pressed against hot areas of the limb. Shock absorbing boot inserts issued prior to initiation of training do not reduce the lower limb pain rate among basic trainees during training.

FY94: Kent Karstetter, MAJ, MC, will become the site PI starting on 5 Aug 94 and ending on 30 Sep 94. No progress reported.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 90/202 (3) Status: Completed

(4) Title: Non-Surgical Treatment of Morton's Neuroma with Injection of Vitamin B-12/Lidocaine/Solumedral Combination

(5) Start Date: 1990 (6) Est Compl Date:1993

(7) Principal Investigator: Kent Karstetter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedic (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The aim of the first phase is to determine whether the injection produces good enough results with a sufficient percent of the patients to be worth giving as a simple first try prior to offering surgery.

(16) Technical Approach: Our plan is to inject a combination of 0.5cc of lidocaine, 0.5cc solumedrol, and 0.5cc of vitamin B-12 into the interdigital neuroma of all patients in a series of two injections.

(17) Progress: The study injection works as a temporary measure at the 90-day followup. Long-term effects cannot yet be determined as the on-year followup data is pending. Dr. Spezia (original PI) has left FAMC. Dr. Karstetter says the study has been completed and will be written up for publication.

Publications and Presentations: Presentation in 1989 at the Barnard Residents's competition.

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 90/204 (3) Status: Ongoing

(4) Title: A Clinical Comparison of a Hydroxylapatite Coated Versus Porous Coated Total Hip Implant for Use in Arthritic Human Hips

(5) Start Date: 1990 (6) Est Compl Date: 1993

(7) Principal Investigator: Edward Lisecki, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators:

(11) Key Words: hydroxyapatite Frederick Coville, COL (RET)

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 96
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Compare results of two porous ingrowth hip components to improve amount of ingrowth, thereby, reduce the need for revisions.

(16) Technical Approach: Posterior approach to the hip routine implantation of a porous femoral/acet. component.

(17) Progress: Hip scores on hydroxy apatite hips is consistently higher than the non HA coated hip. HA hip scores run about 8 points higher than non HA for same time period. No adverse reactions to the HA coating have been found. FY94: Study on hold due to lack of inventory (at manufacturer's end). Study will proceed when inventory problems are solved.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Oct 93 (2) Protocol #: 90/206 (3) Status: Terminated

(4) Title: Pilot Trial of Potentiating Normal Healing of Stress Fractures Using Pulsing Electromagnetic Fields

(5) Start Date: 1990 (6) Est Compl Date: 1995

(7) Principal Investigator: (8) Facility: FAMC/Ft Sill
Richard Sherman, LTC, MS/FAMC
Howard May, LTC, MC/Reynolds ACH, Ft. Sill, OK

(9) Dept/Svc: Orthopedics (10) Associate Investigators:

(11) Key Words:
stress fractures
pulsing magnetic fields

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Oct b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 29
d. Total Number of Subjects Enrolled to Date: 57
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate that a full study of pulsing magnetic fields is warranted for treatment of stress fractures.

(16) Technical Approach: Pulsing electromagnetic fields of two types are being utilized with soldiers having tibial and tarsal stress fractures during basic training at Ft. Sill. One type is generated by an ambulatory device which soldiers strap over their stress fractures and wear for twelve hours per day. The other type is generated by a fixed place device which soldiers come to for one hour per day. An additional third of the participants use the fixed place device but are not aware that the device is not actually generating any fields. The members of the health care evaluative team do not know which participants are in which group so this is a double blind study.

(17) Progress: This phase of the study has only entered 29 of its required 60 subjects. No data have been evaluated yet as most of the subjects are still participating.
FY94: FAMC PI PCS'd to Madigan AMC. No further progress reported.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 90/209 (3) Status: Completed

(4) Title: Reliability of Psychophysiological Mesures Used to Evaluate Pain

(5) Start Date: (6) Est Compl Date: 1995

(7) Principal Investigator:
Richard Sherman, LTC, MS

(8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho

(10) Associate Investigators:
John Arena, Ph.D.
Carson Henderson, Psy.D.
E. Cucinell, COL, MC
Kimford Meador, MD
Jeffrey Ginther, MD

(11) Key Words:
chronic pain
psychophysiological responses
comprehensive assessment

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 51
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: to evaluate the test/retest reliability of several commonly used psychophysiological measures when used with patients and controls.

(16) Technical Approach: Three groups of chronic low back pain subjects, two groups of tension headache and 75 age-matched controls will be assessed five times. The pain groups will be seen three times when at no or low pain levels and twice when at high pain levels. The assessments will consist of the standard six position measurment of surface EMG patterns, standard psychophysiological evaluations and cold presser test.

(17) Progress: Funding arrived 14 June 1991. The first set of data are currently being analyzed. FY94: No progress reported. Project will terminate at FAMC on 5 Aug 94.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 2 Aug 94 (2) Protocol #: 90/210 (3) Status: Terminated

(4) Title: Effectiveness of Treatments for Reflex Sympathetic Dystrophy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Richard Sherman, LTC, MS (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators: Douglas Hemler, MAJ, MC; Kent Karstetter, MAJ, MC; Muhammad Shaukat, LTC, MC; Mary Brinkman, MAJ, RPT; CC Evans, BA; Robert Ketchum, COL, MC

(11) Key Words: reflex sympathetic dystrophy; nerve block; corticosteroids; physical therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 32
d. Total Number of Subjects Enrolled to Date: 42
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the most effective of the standard treatments for reflex sympathetic dystrophy.

(16) Technical Approach: After standard workup and videothermography, subjects will be randomized to one of the three standard treatments--corticosteroids, multiple nerve blocks or vigorous physical therapy. Patients will be followed at 3-mo intervals for one year. If there is no improvement, the patient willbe randomized to one of the remaining treatments.

(17) Progress: This study was suspended during Desert Shield and has gradually been reinstituted as sufficient manpower to perform the medical portions of the program becomes available. PI PCS FY94.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 90/212A (3) Status: Terminated

(4) Title: The Evaluation of Bone Ingrowth in Hydroxylapatite and in Non-Hydroxylapatite Porous Hip Implants in a Goat

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Edward J. Lisecki, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators:

(11) Key Words: bone ingrowth implants

Stephen Cook, PhD
Jerome Weidel, MD

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____40_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To quantify the biomechanical and histological effects of hydroxyapatite on bone growth into porous-coated implants placed in a weight bearing model.

(16) Technical Approach: 40 goats will be assigned to treatment groups 1-5, based upon time to euthanasia. In each group, 4 animals will receive a hydroxyapatite coated implant, and 4 will receive an uncoated implant. Following euthanasia, femurs will be harvested, radiographed, and prepared for biomechanical and histological testing.

(17) Progress: The prostheses which were prepared for the study do not correctly fit the goat. Please terminate this study.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 91/201 (3) Status: Completed

(4) Title: Utilization of Prostheses Among Relatively Healthy Traumatic Amputees

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator: Richard Sherman, LTC, MS (8) Facility: FAMC

(9) Dept/Svc: Orthopedics (10) Associate Investigators: Melissa Daminano, MS Philip Deffer, CPT, MC Stephen Caminer, BS

(11) Key Words: prosthesis amputees

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 175
d. Total Number of Subjects Enrolled to Date: 175
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether those people who are in most need of effective prostheses can use them as required.

(16) Technical Approach: Two phase study to determine the existence of sub-groups of otherwise healthy, working age of amputees who may need different types of prostheses than are currently available. First phase is to reanalyze data from previous surveys. Second phase is to send surveys to all 343 of the soldiers discussed above who had traumatic amputations while on active duty or were otherwise unhurt. This is a pilot study to determine how the questionnaire needs to be revised and to determine how many veterans should receive the questionnaire.

(17) Progress: The initial phase was completed. Virtually all respondents have problems with their prostheses which severely limit utilization and cause disabling pain. The VA did not fund the full study as they feel that this pilot and our previous work demonstrate the point adequately.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 91/203A (3) Status: Terminated

(4) Title: Repair of Femoral Artery by Microvascular Technique in Rabbits and Rats

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: D.E. Casey Jones, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Surg/Orth (10) Associate Investigators:

(11) Key Words: microsurgery

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:___1-2/week_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: This is an ongoing and indefinite study used to maintain proficiency in the microsurgical repair of small vessels, nerves, and tendons. The femoral arteries of rabbits and rats are ideally suited for this type of study and have been used in past years to maintain proficiency for microvascular technique by the Hand Surgery Service of the Orthopedic Service.

(16) Technical Approach: The animals will undergo femoral vessel transection, followed by microvascular surgical anastomosis. After the procedure, the animals will undergo euthanasia while under anesthesia.

(17) Progress: Protocol has been rewritten (see protocol 94/213A).

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 91/204A (3) Status: Completed

(4) Title: Evaluation of a Gelatin Film Barrier Following Parotidectomy for the Prevention of Frey's Syndrome in the Goat (Capra hircus)

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: Vincent Eusterman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Surg/ENT (10) Associate Investigators: Glen Yoshida, MAJ, MC

(11) Key Words: Frey's syndrome

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____6_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Twofold: (1) to develop an animal model to produce post-parotidectomy Frey's Syndrome; (2) to objectively document the ability of a gelatin barrier (Gelfilm), to delay the production of Frey's Syndrome following superficial parotidectomy.

(16) Technical Approach: Superfical parotidectomy on goat bilaterally, gel film placed unilaterally, evaluate sweating with starch/iodine test, sacrifice at intervals to evaluate histology (effect on facial nerve and rate of resorption).

(17) Progress: Frey's Syndrome was not produced in the subject animals. Initial pathology did show dissolutiun of the gel film. Final histology unable to be performed due to lack of technical help and spcimen damage by tissue handler when processing for mailing. Earlier samples salvaged and recut, photos pending.

Publications and Presentations: Presented as poster: American Academy Oto/HNS Washington, DC, Oct 92. Published abstract: Oto/Head & Neck Jornal, August 1992.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 91/206A (3) Status: Terminated

(4) Title: Use of Goats for Training in Advanced Trauma Life Support

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Phillip Mallory, II, LTC (8) Facility: FAMC

(9) Dept/Svc: Surgery/SICU (10) Associate Investigators: Dick Smith, COL, MC

(11) Key Words: advanced trauma life support

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide ealistic training opportunities for physicians in Advanced Trauma Life Support (ATLS) Course.

(16) Technical Approach: Per protocol approved by the LACUC on 12 Aug 91.

(17) Progress: Progress report for FY 93 was not received.
FY94: Outdated protocol administratively terminated by C, IACUC.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 92/200 (3) Status: Terminated

(4) Title: Analysis of Wounds by Evaportive Water Loss in Man: A Pilot Methodology Study

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Henry Jefferson, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Gen.Surg.

(10) Associate Investigators
Sharon Hammond, MAJ, MC
Sam Cucinell, COL, MC
Richard Gonzalez, Ph.D., USAR
Scott Bennion, LTC, MC
Todd Morton, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___OCT____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Develop statistical curve to compare evaporate water loss to wound.

(16) Technical Approach: TWEL device is utilized for this purpose.

(17) Progress: Due to the inability to procure the needed equipment for this protocol, we have been unable to begin work. We have received the equipment as of 23 August 1993 and are currently in the process of understanding the mechanics of the Evaprimeter. We anticipate entering our first patient within the next few weeks.

FY94: The equipment needed did not arrive until late 1993 and was non-functional. Once the equipment was operational multiple technical problems were encountered. To use such a piece of equipment (the Evaprimeter) requires an environment with absolute control to temperature and humidity. No such room exists at FAMC. Aside from this difficulty, the actual application of the device to the wounds in question became near impossible. It soon became apparent that the study designed by COL Cucinell was seriously flawed.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: Jun 94 (2) Protocol #: 92/201 (3) Status: Terminated

(4) Title: Effect of Smoking, Alcohol Ingestion, Radiation Therapy and Beta-Carotene on Langerhans Cells in Human Oral Mucosa: A Pilot Study

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator: Richard Kopke, LTC, MC (8) Facility: FAMC

(9) Dept of SURG/Otolaryngology (10) Associate Investigators

John Peterson, MAJ, MC
Gerald Trammel, COL, MC

(11) Key Words:
langerhans cells
beta carotene
radiation therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 73
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: This study will provide further understanding of the theory of field cancerization by documenting Langerhans cells (LC) response to smoking, smoking and alcohol, irradiation and beta-carotene treatment.

(16) Technical Approach: The density (number) of epithelial LC's will be quantified histologically using 10 random readings from each of three microscopic sections. LC number willbe expressed as number per mm^2 of epighelial surface area of buccal oral mucosa for the following subject groups: 1) habitual smokers (Grp A) vs Grp C (Control); 2) habitual smokers and alcohol users (Grp B) vs Grp C; 3) XTR patients (Grp D) vs Grp C; 4) XRT patients plus beta-carotene (Grp E) vs Grp C; 5) Grp D vs Grp E; 6) Patients in Grp D and Grp E who continue to smoke and use alcohol will be subgrouped and compared to Groups A, B, and C as appropriate.

(17) Progress: Only 3 patients from non-control group have yet to be tested. 85% of the microscopic specimens have been evaluated. The study is nearly completed. Unfortunately, the B-carotene arm had to be dropped due to non-availability of B-carotene. All investigators PCS'd.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 92/202A (3) Status: Ongoing

(4) Title: Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair Utilizing the Rabbit and Rat

(5) Start Date: 1991 (6) Est Compl Date: 1996

(7) Principal Investigator:
Royal K. Gerow, LTC, MC

(8) Facility: FAMC

(9) Dept of SURG/Plastic Surg.

(10) Associate Investigators

(11) Key Words:
microvascular surgery
free flaps, rats

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____20_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To instruct plastic surgery fellows and staff in microvascular surgery and attain and maintain proficiency.

(16) Technical Approach: With anesthetized rats, the femoral artery and veins will be divided and then anastomized using microvascular techniques.

(17) Progress: Integral training of 2 plastic surgery fellows and maintaining proficiency of 4 plastid surgery staff.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Dec 93 (2) Protocol #: 92/204 (3) Status: Ongoing

(4) Title: Effect of Intravenous Erythromycin on Postoperative Ileus

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Joseph Kolb, CPT, MC (8) Facility: FAMC

(9) Dept of SURG/Gen. Surg. (10) Associate Investigators

(11) Key Words: Dr. Hollis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: DEC b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if erythromycin helps resolve post operative ileus.

(16) Technical Approach: This is a randomized, double-blind study.

(17) Progress: Awaiting randomization of specimens. The project is, in essence, ready to begin.
FY94: Study well underway. Ready to evaluate initial data with eight more patients.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Jun 94 (2) Protocol #:92/206 (3) Status: Ongoing

(4) Title: Intraocular Liquid Silicone for Complicated Retinal Detachments. (IDE)

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator: William Waterhouse, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Ophthalm/Surg. (10) Associate Investigators:

(11) Key Words: silicone oil Robert Dragoo, COL, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:June/Jan b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Clinical trial of intraocular liquid silicone for treatment of complicated retinal detachments.

(16) Technical Approach: See protocol.

(17) Progress: 6-month review. Two additional patients were enrolled for a total of ten. FAMC remains the only Army treatment facility which has the ability to treat complicated retinal detachments with silicone oil, thanks to this ongoing protocol. This is a valuable treatment protocol for our patients.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 92/207 (3) Status: Ongoing

(4) Title: Vivonex Ten Versus Immun-Aid in a SICU Population: Effects on Restoring Normal Protein Markers

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Henry Jefferson, CPT, MC (8) Facility: FAMC

(9) Dept of SURG/Gen.Surg. (10) Associate Investigators

(11) Key Words:
protein markers
enteral formulas

Dr. Mallory
Dr. Hammond
Joan Friend

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 13
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Compare two enteral formulas in respect to nutritional aspects.

(16) Technical Approach: Protocol will take place in SICU.

(17) Progress: Nine patients were enrolled with five completed. Protocol will continue until between 10-20 subjects are enrolled.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Feb 94 (2) Protocol #: 92/208 (3) Status: Ongoing

(4) Title: Response of Serum Cytokines in Patients Undergoing Laparoscopic Cholecystectomy to Support the Use of Laparoscopic Techniques for Other Surgery

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator:
John Cho, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Gen. Surg.

(10) Associate Investigators
Dallas Homas, CPT, MC
Jeffrey Clark, COL, MC
Matthew Schofield, CPT, MS
Sharon Hammond, MAJ, MC

(11) Key Words:
cytokines
cholecystectomy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 10
d. Total Number of Subjects Enrolled to Date: 25
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate that the clinical benefits seen in minimally invasive laparoscopic gallbladder surgery versus open cholecystectomy result from a lack of cytokine release leading to attenuation of the acute phase response.

(16) Technical Approach: Measuring 11-6 the acute phase protein-C-reactive protein- and demonstrating a correlation between and a dimunition of cytokine and APP release in laparoscopic versus open cholecystectomy should prove this point.

(17) Progress: Eleven patients enrolld out of 20. Blood being analyzed on six or seven more. Study is almost complete.

FY94: Expect to complete the study by April, 1994. Ten additional subjects enrolled for a total of 25.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 92/209 (3) Status: Ongoing

(4) Title: A Randomized Study of the Stryker OP Device vs Bone Autograft for the Treatment of Tibial Non-Unions

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator: Edward Lisecki, LTC, MC (8) Facility: FAMC

(9) Dept of SURG/Orthopedics (10) Associate Investigators Paul Castello, CPT, MC

(11) Key Words:
non union BMP
IDE

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:MAR/SEP_ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____4_____
d. Total Number of Subjects Enrolled to Date:_____6_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To increase the rate of healing of tibial non unions.

(16) Technical Approach: Non union debridement either use crest graft or OPI.

(17) Progress: Two additional patients enrolled for a total of three. 6-month review: No new patients enrolled. To qualify for study, tibial fractures must fail to unite for 9 months and patients must meet strict qualifying quidelines. The investigators have been in communication with other military hospitals who are cooperating with us to locate potential candidates.
FY94: No adverse events have occurred in the six subjects enrolled to date. Sep 94: FDA recently approved a supplement to the investigational device exemption application. Patients with partial neuropathy may now be included for study; patients with complete neuropathy will be excluded.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 93 (2) Protocol #: 92/210A (3) Status: Ongoing

(4) Title: Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair in Rabbits and Rats

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: Glen Yoshida, MAJ, MC (8) Facility: FAMC

(9) Dept of SURG/Otolaryn (10) Associate Investigators

(11) Key Words:
microsurgical anastomosis, free flalp, small blood vessel repair, never repair

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IACUC Review: MAR b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 4rats
d. Total Number of Subjects Enrolled to Date: 16
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Training of Oto-HNS residents, staff in microsurgical techniques for nerve and vessel repair.

(16) Technical Approach: Transection and repair of femoral nerve, artery, vein of the rat/rabbit utilizing microsurgical techniques.

(17) Progress: Maintenance of microsurgical proficiency has been achieved. Over this period 2 residents received 6 hrs of training.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 May 94 (2) Protocol #: 92/212 (3) Status: Ongoing

(4) Title: The Incidence and Association of Carpal Ligamentous Injuries with Distal Radius Fractures

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator:
John Reiser, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Orthopedics

(10) Associate Investigators
LTC D.E. Casey Jones, MC
MAJ Kevin Rak, MC
MAJ Bernard Borosky, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 31
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the incidence of carpal ligament injury with distal radial and ulnar fractures. Additionally, we will determine the association between the incidence of carpal ligament injury and the classification on severity of distal forearm fractures.

(16) Technical Approach: Data from MRI and radiographic evaluations will be compiled as to severity and classification of the fractures. This data will be analyzed statistically for an association of ligaments injury with distal radial and ulnar fractures, and the incidence with which this association occurs. Carpal ligament injury will be analyzed for association with severity on classification of distal radial and ulnar fractures.

(17) Progress: Twenty-two patients have completed the study. project ongoing. FY94: Over 40 patients now entered in study. Preliminary data was presented at the annual meeting of the American Academy of Orthopedic Surgery in Mar 94. We are currently writing up the data available for submission for publication. an abstract of the data will appear in Orthopedic Transactions this year. Request that the protocol remain open for ongoing data collection.

Publications and Presentations: Presented at the National Hand Surgery Symposium.

Detail Summary Sheet

(1) Date: 7 Jun 94 (2) Protocol #: 92/213 (3) Status: Ongoing

(4) Title: Efficacy of Percutaneous Release of the Trigger Finger: An Anatomic Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Steven Friedel, CPT, MC (8) Facility: FAMC

(9) Dept of SURG/Orthopedics (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JUNE b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 17
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To anatomically check the efficacy of the percutaneous release.

(16) Technical Approach: A percutaneous release will be followed by a standard open release (to determine if the percutaneous release has completely divided the A1 pulley).

(17) Progress: 17 releases have been performed using this protocol. We anticipate doing a power study of our data at 30 cases.

Preliminary data will be presented at the Summer meeting of the Western Orthopaedic Association, July 1993, and the Academy of Surgical Research Annual Meeting, September 1993.

FY94: The study was amended in Jan 94 to add an arm to the study. Working on publishing report for first part and collecting data on the second part.

Publications: None

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 92/214 (3) Status: Terminated

(4) Title: Centocor: HA-1A Efficacy in Septic Shock Trial (CHESS Trial) Centocor Protocol C0041T20 dated 29 May 92.

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Phillip Mallory, LTC, MC

(8) Facility: FAMC

(9) Dept of Surg/General

(10) Associate Investigators
Jack L. DePriest, MAJ, MC

(11) Key Words:
septic shock
HA-1A
monoclonal antibody
investigational new drug

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:Jun/Jan_ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____1_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if the HA-1A monoclonal antibody reduces 14-day mortality in patients with gram negative shock. It is a randomized, placebo-controlled double-blinded study.

(16) Technical Approach: Randomized, placebo-controlled, double-blinded, multi-institutional study.

(17) Progress: After the study was approved, the investigators were informed that the military is not allowed to perform placebo trials without the patient's own consent. Family and guardians are unable to give consent. This simply means that doing almost any meaningful critical care research is impossible, as will be evidenced when this study is complete. Any future involvement in collaborative studies will be a waste of time.

FY94: The sponsor closed the study to patient enrollment in FY93. After data analysis the study was terminated due to significant adverse events in the treatment group.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 92/215 (3) Status: Ongoing

(4) Title: Comparison of Three Pneumatic Compression Devices in 300 Total Hip and Knee Replacement Patients.

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator:
Edward Lisecki, LTC, MC

(8) Facility: FAMC

(9) Dept of SURG/Orthopedics

(10) Associate Investigators
Mark Clyde, CPT, MC
Brad Nelson, CPT, MC

(11) Key Words: pneumatic compression devices

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sep/Mar b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 87
d. Total Number of Subjects Enrolled to Date: 130
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine which three pneumatic compression devices is most effective in preventing DVT.

(16) Technical Approach: Patients will be randomly assinged to one of three pneumatic compression devices following total hip or total knee replacement. Patients will be monitored for clinical sings of DVT. Also, patients will undergo doppler ultrasound if DVT are suspected, or on their 10-14th day post-op.

(17) Progress: FY93: Study is now underway with 43 patients enrolled to date. FY94: 130 patients enrolled to date. Sep 94: Enrollment ongoing. Winner of Barnard and Hugh Mahon Contests, 1994.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Mar 94 (2) Protocol #: 92/216 (3) Status: Ongoing

(4) Title: Comparison of Three Postoperative Autologous Blood Transfusion Techniques (Haemonetics Cell Saver, AUTOVAC LF System, and Stryker ConstaVac System) in 300 Total Hip and Knee Replacements

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Steven Friedel, CPT, MC (8) Facility: FAMC

(9) Dept of SURG/Ortho (10) Associate Investigators

(11) Key Words: Edward J. Lisecki, LTC,MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sep/Mar b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 55
d. Total Number of Subjects Enrolled to Date: 130
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare three methods of postoperative autologous blood transfusion. Methods will be compared for; amount of blood recovered/reinfused; amount of blood bank transfusions required; hemolysis of collected blood product, bacterial contamination of collected blood product; febrile reactions; fat embolism syndrome.

(16) Technical Approach: 300 patients will be randomly assigned to one of three methods of postop autologous blood transfusion following total hip or totoal knee replacement.

(17) Progress: Study ongoing. FY94: Study proceeding according to plan.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 92/218A (3) Status: Ongoing

(4) Title: Effect of Nicotine on Bone Ingrowth and Fixation in Hydroxyapatite Coated and Uncoated Porous Co-Cr-Mo Alloy Implants in a Goat Model

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: Michael P. Grant, CPT, MC (8) Facility: FAMC

(9) Dept of SURG/Ortho (10) Associate Investigators

(11) Key Words:

LTC Edward Lisecki, MC
Stephen D. Cook Ph.D.
MAJ Bert Callahan, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____7_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To quantify the biomechanical and histological effects of nicotine on bone ingrowth and fixation strength of porous coated implants.

(16) Technical Approach: Twenty goats will be randomly assigned to type of treatment (21 mg nicotine/day or control). Four rods which are HA coated for 1/2 of their length will be placed into each femur of each goat. Following euthanasia at 3,6,12,26, or 52 weeks, the implants will be removed and tested for bony ingrowth and fixation strength.

(17) Progress: Initial study has revealed problems with nicotine delivery system. We are investigating possibilities for alternate delivery.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/200A (3) Status: Terminated

(4) Title: Comparison of Healing Rates of Bones Plated Following Fractures, Among Yucatan Swine Having Open and Closed Epiphyses

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
D.E. Casey Jones, LTC, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho

(10) Associate Investigators
CPT Shawn Granger, MC
CPT Bradley Nelson, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____19_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the feasibility of a full study to compare the healing rates in plated long bone fractures before and after physical closure.

(16) Technical Approach: Six mature and six immature pigs will be used. In each pig, the right foreleg radius and ulna will be fractured under direct visualization. All pigs will undergo surgical internal fixation using plates and screws. Euthanasia time will be determined by radiographic examination for callus formation. Healing rates in mature vs immature pigs will be determined by histological examination.

(17) Progress: All surgeries were performed and the animals underwent euthanasia. The bones were misplaced before histological examination could be performed.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/202A (3) Status: Ongoing

(4) Title: Vascular/General Surgery Staff and Resident Training Using Laparoscopic Techniques in the Swine (Sus scrofa)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Sharon L. Hammond, MAJ, MC (8) Facility: FAMC

(9) Dept of SUR/Gen.Surgery (10) Associate Investigators Dr. Philip Mallory

(11) Key Words: laprascopic surgery

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____2_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To train residents and staff on the technical aspects of laparoscopic surgery prior to human application.

(16) Technical Approach: Animal model - Appropriate with laparoscopic surgery.

(17) Progress: Have had recent animal lab with pig - was well attented with good training.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/203A(3) Status: Terminated

(4) Title: Urology Service Training Using Laparoscopic Techniques in the Swin (Sus scrofa)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Ronald Sutherland, MAJ, MC (8) Facility: FAMC

(9) Dept of SUR/Urology (10) Associate Investigators

(11) Key Words:
laparoscopy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:____4 swine_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To train staff and residents on laparoscopic techniques.

(16) Technical Approach: No change from protocol.

(17) Progress: Principal Investigtor has PCSed. We have no information regarding past training. Protocol is closed.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/205A (3) Status: Ongoing

(4) Title: Comparison of Three Sizes of Interference Screws for Graft Fixation of the Central One-Third of the Patellar Tendon in Anterior Cruciate Ligament Reconstruction

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Jack McBride, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (10) Associate Investigators Michael Grant, CPT, MC Richard Sherman, LTC, MS

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____20_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To comapre three different sizes of interference screws for graft fixation of the central one-third of the patellar tendon in ACL reconstruction; to compare cannulated versus noncannulated screws for graft fixation of the central one-third of the patellar tendon in ACL reconstruction.

(16) Technical Approach: Three groups of six goats will be used; groups will be divided based on size of interference screws. A patellar graft will be harvested in bone-tendon-bone construct, placed into a bony tunnel in the tibia, and held in place by an interfernce screw, using an endoscopic interference technique. After the graft is fixed in place, pull-out strength will be established.

(17) Progress: An excess number of tendon ruptures occurred due to the repeated thawing and refreezing of specimens. (Thawing and refreezing were required due to time constraints in performing the procedures). Plan to memo the IACUC to request 30 more specimens on which the study can be repeated without repeated thawing and freezing.

Publications and Presentations: Abstract in J. Invest Surg 6(4):370, 1993.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/206A (3) Status:Completed

(4) Title: Feasibility of the Use of the Immature Pig (Sus scrofa) for Bronchoscopy Training

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Glen Y. Yoshida, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY (10) Associate Investigators

(11) Key Words: Richard D. Kopke, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____2_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Feasibility of using the immature pig for bronchoscopy training.

(16) Technical Approach: See protocol

(17) Progress: The immature pig was found to be suitable for bronchoscopy training. A full protocol will be submitted for consideration.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 Nov 93 (2) Protocol #: 93/208 (3) Status: Ongoing

(4) Title: ^{99m}Tc-HMPAO Labeled Leukocyte Scintigraphy in the Evaluation of Hemodialysis Access PTFE Grafts

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Daniel Clark, CPT, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Gen.Surg.

(10) Associate Investigators
Margaret L. Clark, CPT, MC
Sharon L. Hammond, MAJ, MC
Michael McBiles, LTC, MC
Morakinyo Toney, LTC, MC

(11) Key Words:
hemodialysis grafts
scintigraphy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Nov b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the efficacy of 99mTC-HMPAO leukocyte scintigraphy in evaluating hemodialysis access grafts.

(16) Technical Approach: Per protocol.

(17) Progress: At present, two subjects have been studied with no adverse effects.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 93/209 (3) Status: Ongoing

(4) Title: The Determination of the Amount of Lumbar Root Decompression After Hemilaminotomy and Foraminotomy Versus After Discectomy Using Somatosensory-Evoked Potentials

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Paul Castello, CPT, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho.

(10) Associate Investigators
MAJ Howard Place
MAJ Gary Simonds
MAJ Steven R. Shannon
CPT Robert Williamson

(11) Key Words:
lumbar root decompression
hemilaminestomy
foraminotomy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Nov b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To quantify the lumbar nerve root decompression using SSEP after discectomy, after hemilaminectomy and foraminotomy, and after the combination of the two in consenting patients with herniated lumbar discs who meet the standard objective criteria for surgical treatment.

(16) Technical Approach: Patients will be randomly assigned into two groups. Group 1 will undergo hemilaminotomy and foraminotomy followed by partial excision of the disc. Group 2 will undergo the same procedure in reverse order. Each patient will undergo preoperative, continuous intraoperative, and postoperative SSEP monitoring.

(17) Progress: Study in progress. Results to date show that bony decompression of the neural root is of prime importance when performing nerve root decompression for lumbar herniated nucleus pulposus.

Publications and Presentations: Western Orthopedic Assoc. Snowmass, CO, July-August 1993.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/210A (3) Status: Ongoing

(4) Title: An Attempt at Differentiation of Malignant Glial Cell Tumors in Rattus Norvegicus: A Pilot Study

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Harold B. Vogel, M.D. (8) Facility: FAMC

(9) Dept of SUR/NeuroSurg. (10) Associate Investigators

(11) Key Words:
brain tumor
differentiation

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____45_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Attempt at differentiation of malignant glial tumors in tissue culture by growing them in media which had originally supported the growth of fetal glia.

(16) Technical Approach:
(a) ensure induction of tumors in newborn rats (completed);
(b) growth of fetal glia in tissue and culture and collection of media (completed);
(c) growth of rat brain tumors in tissue culture media obtained in (b), being done;
(d) measurement of change by alternation of flow cytometry and tumor keryotype before and after testing with media obtained in (b), (will follow c).

(17) Progress: All rat experimentation concluded 18 Apr 94. No additional rats purchased during FY94.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 93/211 (3) Status: Ongoing

(4) Title: Effect of Proximal Femoral Cerclage Cable in Femoral Hip Prosthesis Micromotion: A Cadaveric Study

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
David Kim, CPT, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho.

(10) Associate Investigators

(11) Key Words:
cerclage wire
hip prothesis
micromotion

LTC Edward Lisecki, MC
Robert Brown

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To assess if there is any decrease in micromotion of the bone-prosthesis interface after the application of a dall mile cerclage wire.

(16) Technical Approach: Ten proximal femoral cadaveric stems will be examined to insure there are no structural defects. Ten LSF prosthesis will be placed according to manufacturer recommendations. Micromotion will be tested using the instron device in axial and torsional load. Dall mile cerclage wire will be placed and testing will be repeated.

(17) Progress: Results to date show that cerclage wire does not decrease or increase the amount of motion in the constructs.
FY94: No progress. Waiting for machine parts to be able to test added dimensions.

Publications and Presentations: Acad of Surg Research (Breckenridge, CO, 30 Sept -2 Oct 93); Barnard Competition, Mar 93.

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 93/212 (3) Status: Ongoing

(4) Title: Vacuum Therapy Versus Intracavernous Autoinjection of Vasoactive Drugs as the Treatment for Erectile Dysfunction in Diabetic and Anti-Coagulated Patients: A Study of Satisfaction and Safety

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Jerome Limoge, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Urology

(10) Associate Investigators
LTC Diane Henderson
CPT Eric Olin

(11) Key Words:
impotenance
vacuum therapy
intracavernous
anticoagulation

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 9
d. Total Number of Subjects Enrolled to Date: 35
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Safety and satisfaction of injection (intracavernous) and vacuum therapy.

(16) Technical Approach: Patients use ICI or vacuum therapy for 12 weeks each. Diaries are kept, questionnaires completed each 4 weeks.

(17) Progress: To date 35 subjects were enrolled, 9 this report period. Ten patients who tried both therapies decided not to continue in the study. Of the 25 who crossed over, 13 have completed the study.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Mar 94 (2) Protocol #: 93/213 (3) Status: Terminated

(4) Title: A Randomized, Double-Blind, Placebo-Controlled, Partial Crossover Study of Combination Topical Nitroglycerin and Yohimbine Therapy on Erectile Dysfunction in Diabetics

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Christina Manthos, CPT, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Urology

(10) Associate Investigators
Craig Donatucci, LTC, MC
William J. Georgitis, LTC, MC

(11) Key Words:
yohimbine therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Mar b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To see if there is improvement in diabetic patients with enteric dysfunction.

(16) Technical Approach: Per protocol.

(17) Progress: Enrolled and did initial evaluation of 20 patients with H.P. lab tests. All awaiting reception of placebo NTG patches. Because Yocon is a non-patented drug, I solicited several drug companies - only Palisade Pharmaceuticals requested more information, but no product information has been forthcoming. I probably be on clinical hold by the FDA and it will probably be indefinite, unless the Palasades Corporation will provide basic science information. **FY94:** FDA will not approve further clinical testing for yohimbinne; therefore, the project is terminated.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Mar 94 (2) Protocol #: 93/214 (3) Status: Ongoing

(4) Title: Comparison of Cementless Hydroxyapatite-Coated vs Cementless Non-Hydroxyapatite-Coated vs Cemented Ortholoc Advantim Total Knee Systems

(5) Start Date: 1993 (6) Est Compl Date: 1996

(7) Principal Investigator: Edward Lisecki, LTC, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho. (10) Associate Investigators

(11) Key Words:
total knee replacement
hydroxyapatite
cement

CPT Paul Castello

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Mar b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the safety and efficacy of the cementless use of the ortholoc advantin total knee system, with and without HA coating.

(16) Technical Approach: 480 patients will be studied nationwide. 160 will be assigned to the cementless HA device. 160 will be assigned cementless non-HA-coated device, and 160 will be assigned to the cemented device. At FAMC, 40 patients will be assigned to the HA-coated/non HA coated devices.

(17) Progress: Waiting for FDA to assign and IDE #. FY94: FDA approved the study on 18 Feb 94.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 1 Mar 94 (2) Protocol #: 93/215 (3) Status: Ongoing

(4) Title: Comparison of Femoral Hip Prosthesis Micromotion Between Eight Types of Prosthetic Devices: A Cadaveric Study

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
CPT David Kim, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Orthr.

(10) Associate Investigators
Edward Lisecki, LTC, MC

(11) Key Words:
hip prosthesis
micromotion

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Mar b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare the amount of micromotion at the bone-prosthesis interface when using 8 different femoral prosthetic devices.

(16) Technical Approach: 40 proximal cadveric femoral stems will be randomly assigned to one of 8 groups of prosthesis types. Prosthesis will be placed according to manufacturer recommendations. Micromotion will be tested using Instron maxiam and torsional loads.

(17) Progress: No progress to date 2 Sept 1993. FY94: Need devices that will measure 6° of motion. (We can only measure 2°.) Devices are expected soon.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/216A (3) Status: Ongoing

(4) Title: Effect of Ketolorac on Bone Healing Following Simulted Fracture in the Stauffland White Rabbit (Oryctolagus Cuniculi)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Bradley J. Nelson, CPT, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho

(10) Associate Investigators
Michael Moore, MD
Bert Callahan, MAJ, MC
Edward Lisecki, LTC, MC
Howard Place, MAJ, MC
Jim Gebhard, MD

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____41_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the effect of ketolorac on fracture healing in the rabbit.

(16) Technical Approach: 30 rabbits will be assigned to 1 of 3 treatment groups, (high dose ketolorac, low dose ketolorac, or control). A simulated fracture will be made in the right leg of each rabbit. Rabbits will undergo euthanasia at 35 days postop. Femurs will be collected and will undergo mechanical testing.

(17) Progress: Final surgeries were performed in July 1994. After these animals are sacrificed, data analysis will be performed.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/217A (3) Status: Completed

(4) Title: Evaluation of the Endoscopic Screw for Fixation of the Patellar Tendon in Anerior Cruciate Ligament Reconstruction in a Goat Model

(5) Start Date: 1993 (6) Est Compl Date: March 1994

(7) Principal Investigator: Paul H. Castello CPT, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (10) Associate Investigators MAJ Jack McBride, MD

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Animals Enrolled During Reporting Period:__10_____
d. Total Number of Subjects Enrolled to Date:_____10_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the amount of fixation provided by endoscopic screw in the central one-third of the patellar tendon. The results of this study will be compared to those of protocol 90/200A for the interference screw and the suture screw.

(16) Technical Approach: One group of 10 animals will be used. The animals will undergo euthanasia at 0 weeks or 6 weeks. For each animal, the ACC will be reconstructed. Fixation will be achieved using an endoscopic screw.

(17) Progress: Completed all surgeries. Data analysis is underway.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/218A (3) Status: Completed

(4) Title: Evaluation of the Repeat Harvest of the Central One-Third of the Patellar Tendon in a Goat Model

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Jack McBride, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (10) Associate Investigators Bruce E. Piatt, MD Wayne K. Gersoff, MD

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____2_____
d. Total Number of Subjects Enrolled to Date:_____2_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To perfect the technique of repeat harvest of central one-third patellar tendons; to evaluate the strength of a repeat harvest of central one-third patellar tendons which were left open on initial harvest to those which were closed on initial harvest.

(16) Technical Approach: All goats are to have the central thirds of their patellar tendons removed. Tendon defects in the right knees will be left open; tendon defects in the left knees will be closed. After six months, goats will undergo euthanasia. The technique of repeat harvest will be perfected. Then a full study will be proposed.

(17) Progress: Pilot study successfully completed. Protocol for full study is being prepared.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/219A (3) Status: Completed

(4) Title: The Effects of Pentoxifylline on Hyphema in a Rabbit Model (Orytolagus cuniculus)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

(9) Dept of SUR/ (10) Associate Investigators

(11) Key Words:
hyphema
pentoxiphylline

Monte S. Dirks, MD
Eric A. Sieck, MD

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____10_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Study the effects of pentoxiphylline on rabbit traumatic hyphema.

(16) Technical Approach: Laser induced tramatic hyphemas treated with pentoxiphylline.

(17) Progress: Completed.

Publications and Presentations:
International Society of Ocular Trauma; Walter Reed Ocular Trauma Symposium; Colorado Ophthalmological Society Meeting

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/220A (3) Status: Terminated

(4) Title: Effect of Nosteroidal Antiinflammatory Drugs on Bone Ingrowth and Fixation in Hydroxyapatite Coated and Uncoated Porous Co-Cr-Mo Alloy Implants in a Goat Model

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Michael P. Grant, CPT, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho (10) Associate Investigators Edward Lisecki, LTC,MC Stephen Cook, PhD

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To quantify the biomechanical and histological effects of nonsteroidal antiinflammatory drugs on bone ingrowth and fixation strength of porous coated implants.

(16) Technical Approach: 42 goats will be assigned to 1 of 3 treatment groups, according to time of euthanasia. All groups will have 14 animals. Within groups, 2 animals will receive 1 of 7 different NSAIDs. Four rods will be paced into the diaphyseal region of each femur. After euthanasia, rods will undergo biomechanical and histological testing.

(17) Progress: Terminated due to lack of progress in developing assays to detect NSAIDs.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/221A (3) Status: Ongoing

(4) Title: Effect of Nicotine on Soft Tissue Ingrowth and Fixation in a Hydroxyapatite Globe in a Goat Model (Capra hircus)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Stuart R. Farris, MAJ, MC

(9) Dept of SUR/Ophthalmology (10) Associate Investigators

(11) Key Words:
hydroxyapatite orbit implant
nicotine

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:____3_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Assessment of vascularization with and without nicotine.

(16) Technical Approach: Control aspect of study progress.

(17) Progress: 2 pilot animals, 1 control.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 May 94 (2) Protocol #: 93/222 (3) Status: Ongoing

(4) Title: Treatment of Degenerative Spondylolisthesis: A Prospective Comparison of Uninstrumented Posterior Spine Fusion with Decompression, Anterior-Posterior Instrumented Spine Fusion with Decompression, and Instrumented Posterior Spine Fusion with Decompression

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Howard Place, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho.

(10) Associate Investigators
MAJ John Dietz, MC
MAJ David Polly, MC

(11) Key Words:
degenerative spondylolisthesis
spine fusion
decompression

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare 3 surgical methods used to treat degenerative spondylolisthesis in terms of complication rate, long-term relief.

(16) Technical Approach: 50 patients will be randomly assigned to one of three surgical treatments for degenerative spondylolisthesis. Preoperative and postoperative questionnaires will be used to determine which treatment, if any, provides the best long-term relief of symptoms and the least complications.

(17) Progress: Three patients are considering entry into the study.
FY94: No progress.
Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 93/223 (3) Status: Completed

(4) Title: Biofeedback for Pain: A Multipractitioner Outcome Study

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Richard Sherman, LTC, MS

(8) Facility: FAMC

(9) Dept of DCI

(10) Associate Investigators
Frank Andrasik, PhD, U. of FL
John G. Arena, PhD, VAMC, GA
Douglas E. DeGood PhD, U. VA
Alan G. Glaros, PhD, U. MO

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: July b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine the effectiveness of biofeedback techniques as they are actually practiced for control of chronic musculoskeletal low back pain and muscle related orofacial pain. This is intended to be an initial study to test the proposed design, data gathering techniques, and scientist-practitioner interactions as well as to provide sound data on the short term effectiveness of techniques at the borderline between clinical acceptance and research.

(16) Technical Approach: The effectiveness of the techniques as they are actually practiced at this time with the types of patents normally treated by biofeedback practitioners will be established by performing a multipractitioner outcome study. This is intended to assure the rapid and inexpensive acquisition of a large number of subjects while permitting the independent followup of patients required for credibility. Participating practitioners will sequentially enter appropriate subjects and the study team will mail two week pain logs to the patients before, just after, six months after, and one year after treatment.

(17) Progress: No progress FY93, waiting for funding. FY94: This project has been funded by NIH. The majority of practitioners have been recruited and initial forms sent out. The project will move to Madigan AMC at the end of this fiscal year.
Publications and Presentations: None

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 93/224 (3) Status: Ongoing

(4) Title: Control of Swelling After Hand and Foot Surgery for Fractures, Long Bone Fracture Stabilization, and Ankle Sprains Using Pulsed, High Frequency Electromagnetic Energy

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Kent Karstetter, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho.

(10) Associate Investigators
Shawn Granger, CPT, MC

(11) Key Words:
swelling
hand & foot surgery
ankle sprains

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Aug b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether pulsing electromagnetic fields after hand and foot surgery will significantly: (a) decrease the initial amount of swelling, (b) decrease the amount of time the area remains swollen, (c) decrease the intensity of pain and time in pain, (d) increase the rate of return of normal motion, (e) decrease the amount of therapy required for rate of healing of skin and fracture, (f) decrease the amount of therapy required for return of normal motion.

(16) Technical Approach: 400 patients will be randomly assigned to one of two groups. Group I will use the stimulator, but it will not be turned on (control). Group II will use the stimulator and it will be turned on. Swelling will be assessed.

(17) Progress: Study just approved and begun, funding has been approved. Study will start in October 1994.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/225A (3) Status: Completed

(4) Title: Comparison of Two Types of Synthetic Hydroxyapatite Coatings on a Titanium Rod in a Goat Model (Capra hircus)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Edward J. Lisecki, LTC, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho

(10) Associate Investigators

John Kay, PhD
Monica Hawkins, PhD
Vincent Battista, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____9_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare the biomechanical and histological effects of 2 types of synthetic hydroxyapatite coatings on titanium implants in a goat model.

(16) Technical Approach: 9 goats will be assigned to 1 of 3 groups, based upon time to euthanasia. Four rods will be placed into each femur of each goat. Rods will receive either 1 of 2 experimental coatings or not coating (control). At euthanasia, the rods will be removed and will undergo biomechanical and histological testing.

(17) Progress: All surgeries have been performed. Specimens will be returned to study sponsor for final analysis.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/226A (3) Status: Completed

(4) Title: Comparison of Three Types of Synthetic Hydroxyapatite Coatings on a Titanium Rod in a Goat Model (Capra hircus)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator:
Edward J. Lisecki, LTC, MC

(8) Facility: FAMC

(9) Dept of SURGERY/Ortho

(10) Associate Investigators
Paul Serekian, MS
Mark Kester, PhD
Monica Hawkins, PhD
Vincent Battista, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:___9_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare the biomechanical and histological effects of 3 types of synthetic hydroxyapatite coatings on titanium implants in a goat model.

(16) Technical Approach: 9 goats will be assigned to 1 of 3 groups, based upon time to euthanasia. Four rods will be placed into each femur of each goat. Rods will receive either 1 of 3 experimental coatings or not coating. At euthanasia, the rods will be removed and will undergo biomechanical and histological testing.

(17) Progress: All surgeries have been performed. The specimens will be sent to the sponsor for analysis.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 93/227 (3) Status: Ongoing

(4) Title: Comparison of Modulus Compatible Stability (MCS) Porous Coated Hip System Either with or without Hydroxylapatite (HA) Mineral Coating, Placed without Bone Cement; and the MCS Socket Portion, with or without HA Coating, Placed without Bone Cement along with a Cemented Femoral Stem to Stem to Hip Prostheses Placed with Bone Cement

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator: Edward Lisecki, LTC, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ortho. (10) Associate Investigators

(11) Key Words:
total hip replacement
press fit
cement

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 27
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the safety and effectiveness of the MCS total hip system.

(16) Technical Approach: 50 patients will be enrolled from FAMC. 1200 patients will be enrolled nationwide. P.I. will decide whether patients require a cemented or uncemented prosthesis. If P.I. does not use cement, patients will be randomly assigned to receive either a porous coated prosthesis or a porous coated prosthesis with an HA coating.

(17) Progress: Just received committee approval. Will begin very soon.

FY94: To date 24 patients with 27 total hip replacements enrolled.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/228A (3) Status: Completed

(4) Title: Infusion of Neurotrophins and Retinoic Acid into the Perilymph of Guinea Pigs Using a Mini Osmotic Pump

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Richard D. Kopke, LTC, MC

(8) Facility: FAMC

(9) Dept of Surgery/Otolaryngology

(10) Associate Investigators
Ronald Jackson, Ph.D.
Steven Ackley, Ph.D.
David Asher, Ph.D.
Matthew Schofield, CPT, MS

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___SEP____ b. Review Results:_____
c. Number of Animals Enrolled During Reporting Period:_____7_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if neurotrophins and retinoic acid can be infused into the perilymph of guinea pig inner ears via a mini osmotic pump system.

(16) Technical Approach: Under general anesthesia, G.P. cochleas were approached thorough the tympanic bulla. A microcannula was inserted into basal turn of cochlear and radiolabeled compounds were infused into the perilymph via mini osmotic pump.

(17) Progress: Study completed with positive results. Pumps implanted in six animals. Solutions with radioiodinated neurotrophin-3 (C^{125I} NT-3) and retinoicacid (^{3}H-RA) were infused into G.P. cochleas.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/229A (3) Status: Ongoing

(4) Title: Evaluation of the Repeat Harvest of the Central One-Third of the Patellar Tendon in a Goat Model

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Jack McBride, MAJ, MC (8) Facility: FAMC

(9) Dept of SURGERY/Orthopedics (10) Associate Investigators Bruce E. Piatt, MD Wayne K. Gersoff, MD

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 19
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: This study will evaluate (a) the ultimate strength of a repeat harvest of central one-third patellar tendons. (2) the strength of a repeat harvest of central one-third patellar tendons which were left open on initial harvest, compared to that of central one-third patellar tendons which were closed on initial harvest.

(16) Technical Approach: In group I, 10 goats will have the central 1/3 removed from their knees; after removal, the tendons will be left open. In the contralateral control knees, the patellar tendon will be incised, but no material will be excised. In Group II, 10 goats will have the central 1/3 removed from their right knees; after removal the tendons will be closed. In the contralateral knees, the patellar tendon will be incised, but no material will be excised. Al goats will undergo euthanasia 6 months after surgery. The tendons will be harvested for biomechanical analysis.

(17) Progress: 19 animals were used this FY.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/230A (3) Status: Terminated

(4) Title: A Pilot Study to Evaluate the Stauffland Rabbit as a Model for Induced Bipolaris Sinusitis

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Richard D, Kopke, LTC, MC (8) Facility: FAMC Tripler Army Medical Center

(9) Dept of SURGERY/Otolaryngology (10) Associate Investigators Vincent D. Eusterman, LTC, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 4 rabbits
d. Total Number of Subjects Enrolled to Date: 4 rabbits
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if the sinuses of the Stauffland rabbit will develop a fungal sinusitis with a Bipolaris species; to determine if the immunosuppression of the rabbit is required for induction of fungal sinusitis.

(16) Technical Approach:

(17) Progress: Four rabbits were used this report period.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/231A (3) Status: Completed

(4) Title: The Effects of Pentoxifylline on Laser Induced Traumatic Hyphema in a Rabbit Model (Oryctolagus cuniculus)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Larry K. Andreo, CPT, MC (8) Facility: FAMC

(9) Dept of SURGERY/Ophthalmology (10) Associate Investigators Monte S. Dirks, LTC, MC Eric A. Sieck, MAJ, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To assess the effect of Pentoxifylline on traumatic rabbit hyphema.

(16) Technical Approach: Per protocol approved September 1993.

(17) Progress: Completed

Publications and Presentations:

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-200

The Anatomic and Functional Evaluation of Mastectomy Patients by Lymphoscintigraphy: Postoperative Changes and Implications for Therapy

START DATE: Dec 93 EST COMP DATE: Dec 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Chet Morrison, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Gen

ASSOCIATE INVESTIGATORS: Sharon Hammond, MAJ, MC, Mike McBiles, LTC, MC

PERIODIC REVIEW DATE: Dec 93 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: mastectomy, lymphoscintigraphy

OBJECTIVE: To accurately describe and quantify the changes in the lymphatic system of the upper extremity following axillary node dissection with either mastectomy or lumpectomy, and to explore the association, if any, between these changes and the development of clinically impaired lymphatic drainage, also to develop a background for the future evaluation of the effectiveness of various postoperative interventions in the prevention of clinical lymphatic obstruction.

TECHNICAL APPROACH: Three nuclear medicine physicians will be blinded as to pre- and post, and objective signs, such as collateral vessels, will be used to grade the study. The grading will be done separately, and raters will note know one another's scores.

PROGRESS:

Number of subjects enrolled to date: 5
Number of subjects enrolled for reporting period: 5
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Three of the five subjects enrolled have completed the study. Although complete blinded analysis has not yet been formally completed, it appears that two of the three subjects have demonstrated increased lymphatic flow and uptake, which is actually contrary to what would be seen if the original hypothesis was correct; namely a surgical disruption of the lymphatic drainage pathways. The third subject showed decreased lymphatic flow. Of course, more subjects will need to be enrolled before meaningful statistical analyses of these results can be entertained.

PUBLICATIONS: None. PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-201

Comparison of Forearm Movement Using Short-Arm Casts vs Muenster Casts vs Long-Arm Casts

START DATE: Jan 94 EST COMP DATE: Jun 94 STATUS: Completed

PRINCIPAL INVESTIGATOR: Laurette Chang, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Vincent Battista, CPT, MC, D.E. Casey Jones, LTC, MC

PERIODIC REVIEW DATE: Jan 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: fracture immobilization

OBJECTIVE: To compare the amount of forearm motion present in short-arm casts vs Muenster (intermediate length) casts vs long-arm casts.

TECHNICAL APPROACH: Ten subjects without fractures will be measured from pronation to supination using a goniometer prior to immobilization. Each subject will then be placed into the series of three casts and motion measured each time.

PROGRESS:

Number of subjects enrolled to date: 10
Number of subjects enrolled for reporting period: 10
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: All subjects have been measured. FAMC statistician is reviewing data. Plan to submit for publication with the next 6-8 months.

PUBLICATIONS: Barnard competition, Denver, CO, Mar 94.

PRESENTATIONS: "

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-202

A Randomized, Open-Label, Parallel Group Comparison of the Safety and Efficacy of Lovenox (Enoxaparin) Injection vs Coumadin (Adjusted Dose Warfarin) in the Prevention of Thromboembolic Disease Following Hip Replacement Surgery, IND#31532

START DATE: Feb 94 EST COMP DATE: Feb 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Bradley Nelson, CPT, MC

PERIODIC REVIEW DATE: Jan 94 REVIEW RESULTS: Approved
FUNDING: Biomedical Research Foundation of Colorado
GIFTS: NA

KEY WORDS: Lovenox, Coumadin, blood clot

OBJECTIVE: To compare the effectiveness of enoxaparin and warfarin to prevent blood clots following hip replacement surgery.

TECHNICAL APPROACH: Randomized clinical trial of 4,500 patients at 150 medical centers in the US. Thirty patients are expected to be studied at FAMC. Followup exams will occur at 6 and 12 weeks postop.

PROGRESS:

Number of subjects enrolled to date: 11
Number of subjects enrolled for reporting period: 11
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): 2 Jun 94, pt 003, hypoxemia.

Summary of prior and current progress: Currently on schedule to finish 30 patient enrolllment by Jan 95.

PUBLICATIONS: ?

PRESENTATIONS: ?

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-203

An Evaluation of the Lymphatic System in Breast Cancer Patients Undergoing Axillary Lymph Node Dissections: Lymphatic Changes and Implications for Therapy

START DATE: Mar 94 EST COMP DATE: Mar 98 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Sharon Hammond, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Gen Surg

ASSOCIATE INVESTIGATORS: Mike McBiles, LTC, MC, Chet Morrison, CPT, MC

PERIODIC REVIEW DATE: Jan 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: breast cancer, node dissection, lymphatic changes

OBJECTIVE: To get a clearer picture of the changes to the lymphatic system after lumpectomy or mastectomy.

TECHNICAL APPROACH: Using lymphoscintigraphy (LSC), patients undergoing axillary lymph node dissections for breast CA will be studied, focusing on both anatomic changes as well as functional alteration. In part one, pre-op and post op and 6 week LSC evaluation will be obtained, along with upper extremity circumference measurements, and venous duplex somography exams. The latter will document the degree of swelling, and ascertain that the swelling is not from venous obstruction. Patients will be followed for complications of extremity infection and its association with lymphedema. In part two, patients with abnormal LSC at 6 weeks will be randomized to either observation or early lymphatic compression, with compression therapy continuing for one month. Lymphatic function will be reassessed one month following randomization.

PROGRESS:

Number of subjects enrolled to date: 4
Number of subjects enrolled for reporting period: 4
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Enrollment continuing.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-204

Effect of Pre-Surgical Pain Control Training on Recovery

START DATE: Jan 94 EST COMP DATE: Dec 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Janet Wilson, MAJ, AN

FACILITY/DEPT/SVC: FAMC/Surg/Orth Surg

ASSOCIATE INVESTIGATORS: LTC Susan Reznick, MAJ Howard Place, MAJ Lorette Chang, MAJ Charles Hathaway, Richard Sherman, LTC, MS,

PERIODIC REVIEW DATE: Feb 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: relaxation training

OBJECTIVE: To determine whether teaching people (a) to control their pain and stress through relaxation/biofeedback training and (b) about what will happen during their surgery and recovery period (including drains, common vocabulary, likely sensations, time for each stage of recovery, etc.) will significantly reduce (a) need for pain medications, (b) time in the hospital, (c) complications, (d) amount of nursing contact required as well as results in positive changes in other major outcome measures.

TECHNICAL APPROACH: As per objective.

PROGRESS:
Number of subjects enrolled to date: 11
Number of subjects enrolled for reporting period: 11
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Ten control patients have completed the study. Need ten experimental subjects.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-205

Diagnostic and Prognostic Application of Blood Cholesterol and Lactate Measurements in Patients with Undiagnosed Intra-Abdominal Processes

START DATE: Feb 94 EST COMP DATE: Jul 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: David Greco, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Gen Surg

ASSOCIATE INVESTIGATORS: Anne Flynn, MAJ, MC

PERIODIC REVIEW DATE: Feb 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: lab measurements, abdominal pain

OBJECTIVE: To identify any correlation between blood cholesterol, lactate and the diagnosis of abdominal diseases.

TECHNICAL APPROACH: Laboratory study of blood specimens as per title.

PROGRESS:
Number of subjects enrolled to date: 5
Number of subjects enrolled for reporting period: 5
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Difficulty encouraging on-call residents to enroll patients in the protocol. Will continue to educate on-call residents.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-206A

Porous Polyethylene (Medpor) as a Corneal Intrastromal Support for a Keratoprosthesis in the Stauffland Rabbit (Oryctolagus cuniculus)

START DATE: Feb 94 EST COMP DATE: Aug 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Eric Sieck, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophthalm

ASSOCIATE INVESTIGATORS: Robert Enzenauer, LTC, MC, John Miller, Matthew Uyemura, CPT, MC

PERIODIC REVIEW DATE: Dec 93 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: MedPor implants

KEY WORDS: keratoprosthesis

OBJECTIVE: To determine the feasibility of a porous olyethylene intracorneal implant for long-term support of a polymethylmethacrylate (PMMA) keratoprosthesis in a rabbit model. In addition, to quantify the histologic vascular and fibrous ingrowth into the prosthetic material.

TECHNICAL APPROACH: Ten female Stauffland rabbits will be used as experimental subjects with surgical procedures as described in the protocol. Clinical parameters of tissue acceptance, complications, and healing will be observed and recorded. Special attention will be paid to any atrophy, melting, infection, or leaking. Histological examination of the tissue will also be performed.

PROGRESS:

Number of subjects enrolled to date: 10
Number of subjects enrolled for reporting period: 10
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Porous polyethylene stromal supports have been implanted in ten rabbits and two keratoprostheses have been placed. Four rabbits have been euthanized and the studied eyes enucleated.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-207

A Double-Blind, Placebo-Controlled Study to Determine Whether Procrit (Epoetin Alfa) Can Reduce Peri-Operative Transfusion Requirements in Subjects Undergoing Major Orthopedic Surgery. (IND#2318)

START DATE: Apr 94 EST COMP DATE: Apr 95 STATUS: Completed

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: D.E.Casey Jones, LTC, MC

PERIODIC REVIEW DATE: Mar 94 REVIEW RESULTS: Continue
FUNDING: FACT
GIFTS: RW Johnson, procrit

KEY WORDS: procrit, transfusion, surgery

OBJECTIVE: To determine whether Procrit can stimulate the body to produce red blood cells and reduce the number of blood transfusions received following orthopedic surgery. The cost effectiveness of the use of Procrit in orthopedic surgery will be evaluated.

TECHNICAL APPROACH: Subjects will be randomized to receive either a subcutaneous injection of placebo or a weight-dependent dose of Procrit daily for 10 days prior to surgery. Subjects will be given oral iron supplement for at least 10 days prior to surgery. Twelve subjects will be enrolled at FAMC and will be followed for 6 weeks after surgery. Questionnaires will be administered and lab evaluation performed.

PROGRESS:

Number of subjects enrolled to date: 9
Number of subjects enrolled for reporting period: 9
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): case of postoperative ileus with abdominal distension

Summary of prior and current progress: All subjects have been enrolled. Study is complete, except for followups.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-208A

Development of an Infection Resistant External Fixator System and a Tibially Implanted, Percutaneous Limb Prosthetic Holder

START DATE: Feb 94 EST COMP DATE: Dec 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Bendt Peterson, CPT, MC, Richard Sherman, LTC, MS, Stephen Cook, Ph.D. of Tulane University

PERIODIC REVIEW DATE: Jan 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: prosthetic, fixator, implant

OBJECTIVE: Overall to develop a prosthetic attachment system for amputees which can be directly implanted into the major weight bearing bone and be extended through the skin and to develop an external fixator coating which will resist Infection for at least one year.

TECHNICAL APPROACH: Phase III - Test of infection barrier and skin ingrowth using hydroxylapatite coated and uncoated titanium screws implanted percutaneously into goats' bones. Ten goats, half with 4 untreated screws and half with 4 treated screws implanted will be evaluated for an 8-month period.

PROGRESS:

Number of subjects enrolled to date: 2
Number of subjects enrolled for reporting period: 2
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Surgeries have begun. Animals are being observed, but it is too early to draw conclusions.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-209A

Examination of the Effect of Transforming Growth Factor Alpha (TGFα) and Retinoic Acid on Ototoxic Damaged Guinea Pig Neuroepithelium: A Pilot Study

START DATE: Mar 94 EST COMP DATE: Jun 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Richard Kopke, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Otolar

ASSOCIATE INVESTIGATORS: Ronald Jackson, Ph.D., David Asher, Ph.D., Matthew Schofield, CPT, MS, Yehoash Raphael, Ph.D., U of Mich.

PERIODIC REVIEW DATE: Feb 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: neuroepithelium

OBJECTIVE: To determine whether infused perilymphatic transforming growth factor alpha and retinoic acid in combination will induce hair cell regeneration in guinea pig cochleas damaged by kanamycin.

TECHNICAL APPROACH: Nine animals divided into three groups: a control group (C1) and two experimental groups; Experimental 1 - Kanamycin Group (E1) and Experimental 2 (Kanamycin + growth factor group). Mini osmotic pumps will be implanted and infusion administered per experimental design.

PROGRESS:

Number of subjects enrolled to date: 9
Number of subjects enrolled for reporting period: 9
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Nine animals were implanted with miniosmotic pumps; all were given Kanamycin; 6 animals received growth factors. Only one animal should mitotically active cells in damaged cochlea (determined by anti-Brdu analysis. Principal investigator left Jun 94. Will be replaced by Dr. Yoshida.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-210

Efficiency of Three Hearing Instrument Selection Procedures

START DATE: May 94 EST COMP DATE: Jun 95 STATUS: Pending

PRINCIPAL INVESTIGATOR: Dennis Williams, LTC, MS

FACILITY/DEPT/SVC: FAMC/Surg/Audiology

ASSOCIATE INVESTIGATORS: Matthew Brandow, 1LT, MS

PERIODIC REVIEW DATE: Apr 94 REVIEW RESULTS: Pending
FUNDING: NA
GIFTS: NA

KEY WORDS: hearing aids

OBJECTIVE: To determine the clinical accuracy of three hearing instrument selection procedures.

TECHNICAL APPROACH: Retiree at-cost hearing aid program subjects divided three groups, 50 subjects each: Audiogram Procedure, Real Ear Unaided Response (REUR) Procedure, and REUR/Real Ear Coupler Difference (RECD) Procedure.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: No progress. Study not started.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-211

Use of Pulsing Electromagnetic Fields for the Treatment of Limb Pain

START DATE: May 94 EST COMP DATE: May 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Kent Karstetter, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Jeffrey Hrutkay, MAJ, MC, Bendt Peterson, CPT, MC, FAMC; Richard Sherman, LTC, MS, D.E. Casey Jones, LTC, MC, Madigan AMC; Jeffrey Ginther, LTC, MC, Evans ACH; Steve Pals, MAJ, MC, Scott Schaffer, 1LT, MPT, Reynolds ACH

PERIODIC REVIEW DATE: Apr 94 REVIEW RESULTS: Approved
FUNDING: MRDC ?
GIFTS: Loan of equipment

KEY WORDS: pain control, electromagnetic fields

OBJECTIVE: The overall objectives of the program are to determine whether pulsing electromagnetic fields, (PEMFs) can reduce swelling after hand, ACL, and foot surgery of simple fractures of the long bones faster and further than standard techniques and reduce the recovery time after stress fractures and ACL related knee pain.

TECHNICAL APPROACH: Swelling of the involved limb will be measured either by submersion in water, by pressure sensor called a "cast alert" or algometer. Photographs will be taken of the surgical site. Subjects will participate for 1 1/2 hours per day for a maximum of 2 weeks. The limb will be inserted in the PEMF for one hours and measurements for 15 minutes.

PROGRESS:
Number of subjects enrolled to date: ?
Number of subjects enrolled for reporting period: ?
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: The PI did not submit a report.

PUBLICATIONS: ?

PRESENTATIONS: ?

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-212

Comparison of Stiffness in Distal Radius Fractures After Injection of Steroid, Injection of Lidocaine, or No Injection at Time of Immobilization

START DATE: Jun 94 EST COMP DATE: Jun 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Jeffrey Hrutkay, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: David Kim, CPT, MC, William Pace, CPT, MC, D.E. Casey Jones, LTC, MC (Madigan AMC)

PERIODIC REVIEW DATE: May 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: fracture, inflammation, steroid, lidocaine

OBJECTIVE: To compare the stiffness which occurs during healing of distal radius fractures after injection of steroid, injection of lidocaine, or no injection at time of immobilization.

TECHNICAL APPROACH: Ten patients will be initially assigned to each of three groups. All patients will undergo hand/wrist evaluation at discontinuance of immobilization, at 8 wks, at 12 wks, and at 6 months folling fracture. Wrist motion, digital motion, grip strength, and pinch strength will be evaluated and compared with the unfractured contralateral limb as a control. The percent differences will be compared between groups to determine if they show statistical significance.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Waiting for possible funding from Women's Research Initiative or from VA/DOD application.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-213A

Repair of Rat Femoral Artery and Rabbit Auricular Artery by Microvascular Technique

START DATE: May 94 EST COMP DATE: Indef. STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Steven Topper, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: May 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: surgical training, microvascular technique

OBJECTIVE: Ongoing training of Hand Surgery Service to maintain proficiency in the microsurgical repair of small vessels, nerves and tendons.

TECHNICAL APPROACH: Arteries of 0.7 mm to 1.2 mm in diameter will undergo transection, followed by microvascular surgical anastomosis.

PROGRESS:
Number of subjects enrolled to date: 9
Number of subjects enrolled for reporting period: 9
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Protocol is ongoing.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-214A

Effects of Increased Levels of Glutathione on Traumatic Cataracts in Albino Rats (Rattus Norvegicus)

START DATE: 1 Aug 94 EST COMP DATE: 15 Oct 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Larry Andreo, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophth

ASSOCIATE INVESTIGATORS: Monte Dirks, LTC, MC

PERIODIC REVIEW DATE: Jul 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: cataracts, glutathione

OBJECTIVE: To determine the effects of increased glutathione levels on the density and resolution of traumatic cataracts in white rats.

TECHNICAL APPROACH: Pilot study using 5 rats in the treatment group and 5 as controls, followed one month later using the remaining 18 rats.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Not started.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-215A

Effects of 5-Fluorouracil on Adhesion Characteristics in Strabismus Surgery in the Stauffland Rabbit (Oryctolagus cuniculus)

START DATE: 1 Sep 94 EST COMP DATE: 1 Oct 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Larry Andreo, CPT, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophth

ASSOCIATE INVESTIGATORS: Monte Dirks, LTC, MC

PERIODIC REVIEW DATE: Jul 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: strabismus, adhesion, 5-fluorouracil

OBJECTIVE: To assess the impact of anti-fibroblastic agents such as 5-FU on the strength and extent of scarring of extraocular muscles and conjunctiva in strabismus eye surgery.

TECHNICAL APPROACH: One half of the attachments will be treated with 5-FU and will be compared for strength of attachment and scarring the attachments not treated with 5-FU.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Not started.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-216

A One-Year, Parallel, Randomized, Double-Masked, Active-Controlled, Multiclinic Study Comparing the Corneal Safety of 2% MK-507 Ophthalmic Solution, 0.5% Timolol Ophthalmic Solution, and 0.5% Betaxolol Ophthalmic Solution in Patients with Elevated Intraocular Pressure with Ocular Hypertension or Glaucoma. (IND#46,041-MK 0507, 048-01)

START DATE: ? EST COMP DATE: ? STATUS: Pending

PRINCIPAL INVESTIGATOR: Monte Dirks, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Ophthal

ASSOCIATE INVESTIGATORS: Robert Dragoo, COL, MC, Eric Sieck, MAJ, MC, John Brozetti, MAJ, MC, Jeffrey Heier, CPT, MC, Larry Andreo, CPT, MC

PERIODIC REVIEW DATE: Sep 94 REVIEW RESULTS: Tabled
FUNDING: ?
GIFTS: ?

KEY WORDS: glaucoma

OBJECTIVE: ?

TECHNICAL APPROACH: ?

PROGRESS:
Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: NA

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-217A

Evaluation of Bilateral Oophorectomy with and without a High Phosphorous Diet for the Induction of Osteoporosis in Mature Female Goats

START DATE: Aug 94 EST COMP DATE: Aug 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Vincent Battista, CPT, MC

PERIODIC REVIEW DATE: Aug 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: osteoporosis, oophorectomy, diet

OBJECTIVE: (1) To provide a comparison of bone tissue from steroid-induced osteoporosis vs oophorectomy-induced osteoporosis. (2) To determine whether the use of steroids vs the use of oophorectomy would be the most rapid way to induce osteoporosis. (Data from this study to be compared to concurrent steroid protocol.)

TECHNICAL APPROACH: Four goats will undergo bilateral oophorectomy. Two will receive a high phosphorous diet and two will receive a standard diet. The presence of osteoporosis will be determined through a transiliac crest biopsy and a Lunar DPXL bone scan to be performed at baseline, 2 weeks after oophorectomy, and monthly thereafter.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None

Summary of prior and current progress: Not started yet.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-218A

Refinement of the Surgical Technique for the Implantation of Two types of Lumbar Vertebral Prostheses in a Goat Model (Capra hircus)

START DATE: Aug 94 EST COMP DATE: Aug 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Howard Place, MAJ, MC, Mark Clyde, CPT, MC, Vincent Battista, CPT, MC

PERIODIC REVIEW DATE: Aug 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: surgical technique

OBJECTIVE: (1) To refine the surgical technique for the implantation of experimental lumbar prostheses. (2) To refine the techniques for histological and biomechanical analyses of the implants.

TECHNICAL APPROACH: Four goats will receive a lumbar vertebral prosthesis. In Group I, two goats will receive an implant which will replace a disk at the L4-L5 junction. In Group II, two animals will receive an implant which will be inserted through the axial plane of the vertebral body of the L4 vertebra. Euthanasia will occur 6 weeks after implantation. The implants will undergo histological and biomechanical testing.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Study just approved.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-219A

Determination of the Optimum Dosing of Solu-Medrol (Methylprednisolone Sodium Succinate) Required to Induce Osteoporosis in Mature Female Goats

START DATE: Aug 94 EST COMP DATE: Aug 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Edward Lisecki, LTC, MC

FACILITY/DEPT/SVC: FAMC/Surg/Orth

ASSOCIATE INVESTIGATORS: Vincent Battista, CPT, MC

PERIODIC REVIEW DATE: Aug 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: osteoporosis

OBJECTIVE: (1) To determine the dosage of Solu-Medrol which is required to induce osteoporosis in the goat. (2) To provide a comparison of bone tissue from steroid-induced osteoporsis vs oophorectomy-induced osteoporosis. (3) To determine whether the use of steroids vs the use of oophorectomy would be the most rapid way to induce osteoporosis in the goat. (data from this study will be compared to concurrent oophorectomy protocol.)

TECHNICAL APPROACH: Four goats will receive 60 mg/day of Solu-Medrol and two will receive 120 mg/day. The presence of osteoporosis will be determined through a transiliac crest biopsy and a Lunard DPXL bone scan to be performed at baseline, 2 weeks after oophorectomy, and monthly thereafter.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: No progress yet. Study just approved.

PUBLICATIONS: None.

PRESENTATIONS: None.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/355A (3) Status: Terminated

(4) Title: Investigator Training Using Laparoscopic Techniques in the Swine (Sus scrofa)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Harry C. Crawford, LTC, MC (8) Facility: FAMC

(9) Dept of SUR/ (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Teach resident staff surgical procedures on ureter, bladder and bowel.

(16) Technical Approach: Open abd. surgery under general anesthesia.

(17) Progress: Good, Residency program ended.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 May 94 (2) Protocol #: 93/356 (3) Status: Ongoing

(4) Title: Correlation Among Parity, Exercise, Age and Urinary Incontinence in the Female Military Member: A Pilot Study

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator: Gary Davis, LTC, MC (8) Facility: FAMC

(9) Dept of OB/GYN (10) Associate Investigators

(11) Key Words:
urinary incontinence

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 150
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the rate of urinary incontinence in female military members.

(16) Technical Approach: Questionnaires are given to participants after the standard PT test.

(17) Progress: Greater than 150 surveys were returned during the last PT test. We will hand out approximately 200 during the October PT test. FY94: PI wishes to extend this study past the April PT test in order to obtain new subjects and more surveys.

Publications and Presentations: Will be presented at the 1994 Army ACO meeting.

Detail Summary Sheet

(1) Date: 30 Sep 93 (2) Protocol #: 93/357 (3) Status: Ongoing

(4) Title: Quantitation of Urinary Incontinence During Exercise in the Female Military Member

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator:
Gary Davis, LTC, MC

(8) Facility: FAMC

(9) Dept of OB/GYN

(10) Associate Investigators

(11) Key Words:
quantitation of incontinence

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Quantify incontinence during simulated PT test in military females complaining of incontinence.

(16) Technical Approach: Pad weighing during exercise.

(17) Progress: 14 subjects have completed the study.
FY94: Only 5 more subjects have completed this study. PI will attempt to isolate more after the next PT test in April.

Publications and Presentations: Plan to present results at the 1994 ACO Army meeting.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-350

Fetal Movement Rates at High Altitude, a Pilot Study (Replication of Moore and Piacuardio (1989) Study, at High Altitude)

START DATE: Nov 93 EST COMP DATE: Feb 94 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Gary Davis, COL, MC

FACILITY/DEPT/SVC: FAMC/Ob-Gyn/OB

ASSOCIATE INVESTIGATORS: Christine Hansen, MD

PERIODIC REVIEW DATE: Nov 93 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: fetal movements, altitude

OBJECTIVE: The purpose of this pilot study is to validate a protocol in which the patient will be instructed to record the lapsed time required to appreciate 10 fetal movements. The mean time interval will be established, as well as the standard deviation at elevations above 5000 feet (high altitude).

TECHNICAL APPROACH: A sample of 100 available pregnant women receiving obstetric care at FAMC, with fetal gestational ages starting at 28 weeks, will be asked to volunteer. All participants must reside in areas with an altitude of 5000 feet or greater.

PROGRESS:
Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: None.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-351

The Fetal Acoustic Stimulation Test (FAST) as a Screening Test for Fetal Well Being - A Pilot Study

START DATE: Apr 94 EST COMP DATE: Jul 94 STATUS: Withdrawn

PRINCIPAL INVESTIGATOR: David Marden, CPT, MC

FACILITY/DEPT/SVC: FAMC/Ob-Gyn/Ob

ASSOCIATE INVESTIGATORS: None.

PERIODIC REVIEW DATE: Apr 94 REVIEW RESULTS: Pending
FUNDING: NA
GIFTS: NA

KEY WORDS: fetal health, fetal acoustic stimulation test

OBJECTIVE: To assess usefulness of FAST as a screening test for fetal well-being.

TECHNICAL APPROACH: A sample number of 100 volunteers greater than 30 weeks gestation will be evaluated by a fundal height measurement and doppler enhanced auscultation of the fetal heart. FAST will be done after the fundal height is measured and before fetal heart tones are assessed.

PROGRESS:

Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Terminated due closure of the OB-Gyn Residency Training Program.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR GYNECOLOGY ONCOLOGY GROUP PROTOCOLS

Gynecology Oncology Group Protocols. **Ongoing.**

80/351 GOG 26A	87/358 GOG 93	89/352 GOG 101
80/352 GOG 26C	87/359 GOG 99	89/356 GOG 102F
80/359 GOG 26S	88/350 GOG 92	90/351 GOG 109
87/353 GOG 90	88/358 GOG 100	91/350 GOG 26II
87/354 GOG 95	88/359 GOG 102A	91/352 GOG 102H
91/353 GOG 109	93/352 GOG 120	
91/357 GOG 26LL	93/353 GOG 132	
92/351 GOG 119	93/354 GOG 134	
93/351 GOG 114		

Gynecology Oncology Group Protocols. **Completed** (Closed).

89/351 GOG 87D	90/352 GOG 26EE	90/354 GOG 26HH
90/355 GOG 102G	90/350 GOG 26II	91/351 GOG 26JJ
91/354 GOG 110	91/355 GOG 112	91/359 GOG 87F
90/353 GOG 26GG	80/384 GOG 78	92/350 GOG 26MM

START DATE: 1980 EST COMP DATE: Indefinite STATUS: As noted above.

PRINCIPAL INVESTIGATOR: Francis Major, MD

FACILITY/DEPT/SVC: FAMC/Surg/Gyn

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: 3 May 94 REVIEW RESULTS: Noted above.
FUNDING: NA
GIFTS: NA

KEY WORDS: cancer

OBJECTIVE: Cancer treatment.

TECHNICAL APPROACH: Per NCI protocol.

PROGRESS:
Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor: NA

Summary of prior and current progress: No new subjects enrolled since the elimination of the position of gynecology oncologist at FAMC.

PUBLICATIONS: None. PRESENTATIONS: None.

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 77/300 (3) Status: Completed

(4) Title: Immunologic Disorders in Children and Adults. I. Correlation of Immune Function in the Immunodeficiency State. II. Correlation of Immune Function of Leukemia and other Childhood Malignancies

(5) Start Date: 1977 (6) Est Compl Date: Open-Ended

(7) Principal Investigator: Michael Lieberman, LTC, MS (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators Nicholas Battafarano, MAJ, MC Amy Ellingson, CPT, MC

(11) Key Words immunologic diseases

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 73
d. Total Number of Subjects Enrolled to Date: 1614
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Existing specialized immunochemical procedures will be consolidated into a registered protocol for use on a consultative basis by the FAMC hospital staff.

(16) Technical Approach: Serum gammapathics evaluated by SPEP, IEP, and rate nephelometry. Lymphocyte phenotyping, DNA analysis, and neutrophil activation potential by flow cytometry. Lymphocyte activation determined by quantitative mitogenesis.

(17) Progress: Data collection and analysis continues with four presentations in 1993. FY94: IRC recommended that the protocol be rewritten to reflect changes in patient population at FAMC and to update to include new laboratory tests.

Presentations:

(1) Brown, G.L., and Heggers, J.: Medical Mycology: Assessment of Bacteriologic and Serologic Parameters of Clinically-important Mycoses Normal and Immunologic Comprised Host. Presented: American Medical Technologist Educational Seminars, Denver, CO, July 1979.

(2) Dolan, W., Hill, S., Hasbargen, J., Rickman, W., and Weber, R.: Ac-quired Hypogammaglobulinemia with Absence of Leu-12 Antigen Following Bilateral Nephrectomy and Renal Transplantation for Goodpasture's Syndrome. Presented: 14th Annual Allergy-Immunology Symposium, Aurora, CO, 21-23 January 1986.

(3) Rickman, W.J., Lima, J.E., and Muehlbauer, S.L.: U.S. Army HTLV-III Testing Program Flow Cytometry Workshop. Presented: 11th Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists, San Antonio, TX, 18-20 March 1986.

(4) Rickman, W.J.: Epidemiology, Pathogenesis and Military Implications of HTLV-III Infection. Presented: Health Service Command Annual Pharmacy Conference. Aurora, CO, 5-9 May 1986.

(5) Rickman, W.J., Harrison, S.M., Lima, J.E., Muehlbauer, S.M., and Schaff, R.: Lymphocyte Subsets in Human Immunodeficiency Virus Infection: A Prospective Study. Presented: 2nd Annual Symposium of the Rocky Mountain Flow Cytometry Users Group, Albuquerque, New Mexico, 10-11 September 1986.

(6) Rickman, W.J., Harrison, S.M., Lima, J.E., Muehlbauer, S.M., and Schaff, R.: Human Immunodeficiency Virus (HIV) Natural History Study: Abnormal Proliferation of Leu-7 Positive Suppressor T Cells in Asymptomatic Seropositive Patients. Presented: United States Army AIDS Conference, Arlington, VA, 16-18 September 1986.

(7) Stewart, RS, and Hoyt, AJ: Utilization of an Automated Windowless Geiger Chamber Apparatus In Lieu of Liquid Scisntillation for Lymphocyte Transformation Assays. Presented: 15th Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists. Baltimore, MD, March 1990.

(8) Battafarano, NJ, Muehlbauer, SL, Lima, JE, Hoyt, AJ, Albano, EA, Lieberman, MM, Goodman, DL: Immunodeficiency with Hyper-IgM: Pathophysiology and Response to Therapy. Presented: Seventh Annual Harold S. Nelson Allergy-Immunology Symposium (21st Annual Meeting of the Association of Military Allergists), February, 1993, Aurora, CO.

(9) Battafarano, NJ, Muehlbauer, SL, Lieberman, MM, Albano, EA, Goodman, DL: Immunodeficiency with Hyper-IgM. Presented: American Academy of Allergy and Immunology Annual Meeting, March, 1993, Chicago, IL.

(10) Battafarano, NJ, Muehlbauer, SL, Lima, JE, Hoyt, AJ, Lieberman, MM, Goodman, DL: Lymphocyte Functional Studies in Immunodeficiency with Hyper-IgM. Presented: American Association of Immunologists/Clinical Immunology Society Joint Annual Meeting, May 1993, Denver, CO.

(11) Battafarano, NJ, Ellingson, A, Muehlbauer, SL, Lima, JE, Hoyt, AJ, Goodman, DL, Lieberman, MM: Immunodeficiency with Hyper-IgM: Pathophysiology and Response to Therapy. Presented: Aspen Allergy Conference, July, 1993. Aspen, CO.

Publications:

Smolin, MR, Rickman, W, Hasbargen, J: Hypogammaglobulinemia in a Renal Transplant Recipient with Antiglomerular Basement Membrane Disease. Am. J. Kid. Dis., 11:267-269, 1988.

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 82/302 (3) Status: Ongoing

(4) Title: The Evaluation of Recently Introduced, Commercially Available Clinical Microbiology Products for Possible Use in the FAMC Diagnostic Microbiology Laboratory

(5) Start Date: FY 84 (6) Est Compl Date: Ongoing

(7) Principal Investigator: LTC Richard Harris (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators

(11) Key Words: microbiology, microbiological techniques — Donald D. Paine, DAC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JULY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate introduced products which are of interest to the Microbiology Service, Department of Pathology, FAMC, but which cannot adequately be evaluated within the laboratory due to time, personnel, and monetary constraints. This evaluation will include cost effectiveness, ease of use, reproducibility and speed.

(16) Technical Approach: A separate protocol will be designed for each product evaluated.

(17) Progress: Evaluation of a ELISA kit (Ortho) for the measurement of antibody to hepatitis C (formerly non-A, non-B). This kit appears useful for large scale screening but is not specific enough for confirmation of Hepatitis C. Evaluation of a western blot kit (CHIRON-RIBA) for the measurement of antibody to Hepatitis C in sera. This kit appears to be more specific than the ELISA (ORTHO). We recently evaluated a second generation Western Blot kit (CHIRON-RIBAII) and found it to be more sensitive in detecting antibodies to Hepatitis C in serum than the original RIBA method. Several kits are under consideration including Hepatitis D and a DNA probe for H. influenza.

Progress continued -

Evaluation of an ELISA kit (Whittaker), RheumELISA, for the detection of autoantibodies to Sm, RNP, SS-A/Ro, SS-B/La. Patients with a positive ANA screen were tested using this kit. It was found to be too sensitive for clinical use. Several kits are under consideration for evaluation inlcuding an ELISA for Helicobacter pylon.

Evaluation of new Group A streptococcus rapid test procedure is in progress in coordination with the Dept of Pediatircs.

FY94: Completed study of rapid Group A Strep test supporting Department of Pediatrics which was presented at the May 94 meeting of the American Society of Microbiology in Las Vegas. Performing study on new susceptibility test for bacteriology specimens.

Presentations:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur,J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococci by Direct Swab Micronitrus Acid Extraction Technique. Presented: a) Uniformed Services Pediatric Seminar, Norfolk, VA, March 1985; b) 5th Annual Conference on Military Pediatrics Research, Aspen, CO, July 1985;) 14th Aspen Conference on Pediatric Research, Aspen, CO, July 1985.

Harris, R: Impact of Rapid Group A Strep Optical Immunoassay Test on Antibiotic Usage in Pediatric Clinics. Am Society of Microbiology, Las Vegas, NV, May 94.

Publications:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococcus by Direct Swab Micronitrus Acid Extraction Technique. J. Clin. Microbiol.

Detail Summary Sheet

(1) Date: 1 Feb 94 (2) Protocol #: 89/302 (3) Status: Ongoing

(4) Title: Biology of Cutaneous Lupus: II Characterization of Autoantigens and Autoantibodies in Lupus

(5) Start Date: 1989 (6) Est Compl Date: 1994

(7) Principal Investigator: Scott Bennion, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators:

(11) Key Words:
neonatal lupus erythematosus
autoantigens
autoantibodies
Ro

Lela Lee, MD, UCHSC
Ann Hoyt
Michael Lieberman, LTC, MS
Kathleen David-Bajar, MAJ,MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The major objectives of this project are to characterize the autoantigens and autoantibodies involved in neonatal lupus erythematosus (NLE) and subacute cutaneous lupus erythematosus (SCLE) and to determine if certain characteristics of the autoantigens or autoantibodies can be related to the major clinical findings in these diseases.

(16) Technical Approach: Immunoblotting technique, cloning of Ro, rabbit immunization with Ro to attempt to produce animal model.

(17) Progress: Techniques of Western Blotting are being improved, including comparison of different antigen extracts. Additional patients with subacute cutaenous lupus erythematosus and neonatal lupus erythematosus have been evaluated with Western Blotting. No progress since the FY93 Annual Progres Report.

Presentation: European Society for Dermatologic Research, Copenhagen, Denmark, June 1991. "Subacute cutaneous lupus erythematosus is distinguishable clinically, histologically, and by immunofluorescence".

Abstract: David KM, Bennion SD, DeSpain JD, Golitz LE, Lee LA: Subacute cutaneous lupus erythematosus is distinguishable clinically, histologically, and by immunofluorescence.

Publication: David-Bajar KM: Subacute cutaneous lupus erythematosus. J Invest Dermatol 100:2S-8S, 1993.

Detail Summary Sheet

(1) Date: 1 Feb 94 (2) Protocol #: 89/303 (3) Status: Terminated

(4) Title: Biology of Cutaneous Lupus: III The Study of the Effects of Ultraviolet Light on the Skin of Lupus Erythematosus Patients

(5) Start Date: 1989 (6) Est Compl Date: 1993

(7) Principal Investigator:
Scott Bennion, COL, MC
Lela Lee, MD

(8) Facility: FAMC
UCHSC

(9) Dept/Svc: Dept Clin Invstgn

(10) Associate Investigators:

(11) Key Words:
ultraviolet light
cutaneous lupus

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To investigate and better correlate the cutaneous lupus subsets with their respective responses to ultraviolet light to be performed by phototesting patients with systemic lupus erythematosus (SLE), discoid lupus erythematouss (DLE) and subacute cutaneous lupus erythematosus (SCLE) then analyzing tissue and serologic specimens.

(16) Technical Approach: UV exposure followed by immunfluoresenct.

(17) Progress: Since last protocol summary no progress has been made. We continue to encounter the same problems as noted earlier. We have been unable to find a patient to determine UV dosage. We wish to extend the protocol an additional year during which we hope to find a suitable subject; if no subject can be found within the year, we will terminate the protocol. The data collected by such a protocol would be valuable since no previous studies in this area have been done. Terminated FY94.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Jun 94 (2) Protocol #: 91/300 (3) Status: Ongoing

(4) Title: Prospective Collection and Banking of Lymphocytes and Clinical Data on HIV Infected Individuals Taking Antiretroviral Agents

(5) Start Date: 1991 (6) Est Compl Date: 1997

(7) Principal Investigator: Wheaton Williams, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators: David Cohn, MD, DH&H Chip Schooley, MD, UCHSC Douglas Mayers, MD, WRAIR Harris, Richard W., LTC, MS

(11) Key Words: antiretroviral

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a resource collection of lymphocytes and clinical information on HIV infected patients who are taking antiretroviral agents in known amounts and duration on other protocols.

(16) Technical Approach: Update of history and physical parameters every 12 weeks, collection of 2 x 10^7 lymphocytes after CD4 helper enumeration, beta-2 microglobulin and P24 antigen every 12 weeks, chem 18 every 12 weeks, skin testing every 12 weeks (desirable but not essential).

(17) Progress: Banking of lymphocytes and collection of clinical data is successfully progressing with a total of 650 patients currently enrolled, 6527 separate data collection times and over 38,000 specimens banked for serum and/or lymphocytes. FAMC Data Base for patient history and plasma/serum/cell collection is being integrated into the central MMCAR data base in coordination with Program area 2. We are initiating a collaboration with Dr. Vahey, Program area 5 in corrdination with Wilford Hall (Dr. Melcher). FAMC Data Base files have been sent to the Area 5 Data Manager. We are planning a coordinated evaluation of the FAMC plasma/serum/cell bank for evaluation of surrogate markers in long term HIV patients.

Presentation: The Duration of Clinical Stabilization with AZT Therapy; D.L Mayers et al: International HIV Conference.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 91/302A (3) Status: Completed

(4) Title: Training for Department of Clinical Investigation and Veterinary Services Personnel in Medical, Surgical, and Emergency Care and Treatment, and Laboratory, Pathology, and Radiologic Procedures for Various Laboratory Animal Species

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Kevin D. Corcoran, MAJ, VC (8) Facility: FAMC

(9) Dept/Svc: CI/Animal Res (10) Associate Investigators: Marta Acha, CPT, VC

(11) Key Words: training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____34_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide in-house training in animal specific procedures to animal technicians and animal care providers.

(16) Technical Approach: 9 ferrets, 9 goats, 9 guinea pigs, and 3 rats were used for training in husbandry, restraint and phlebotomy techniques.

(17) Progress: Training was conducted to familiarize staff with required techniques.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 92/300 (3) Status: Ongoing

(4) Title: Studies on Mycobacterium avium. I. Determination of the Minimum Inhibitory Concentration (MIC) and the Minimum Bactericidal Concentration (MBC) of Various Anti-Mycobacterial Agents and Synergistic Effects with Combinations of Agents

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Michael Lieberman, LTC, MS (8) Facility: FAMC

(9) Dept of DCI (10) Associate Investigators

(11) Key Words:

antibiotic synergy
mycobacterium avium

LTC Richard Harris, MS
Donald Paine, DAC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: (1) Determine values for the MICs and MBCs for each antibiotic with each of the study strains of M. avium; (2) calculate the MIC 90 and MBC 90 values for each antibiotic (the MIC or MBC for at least 90% of the strains, respectively); (3) calculate an index of synergy for various combinations of anti-mycobacterial agents by determining MIC and MBC values for each agent in the presence of fractional MIC or MBC concentrations of the other agents and in the absence of other agents.

(16) Technical Approach: Laboratory benchwork as described in technical detail in the protocol methodologies.

(17) Progress: MIC's of 7 antimycobacterial agents have been determined for 3 strains of M. avium and the synergistic potential of various combinations of two of these antibiotics determined. However, further progress is delayed indefinitely due to lack of personnel to support this protocol.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 92/301 (3) Status: Ongoing

(4) Title: Molecular Epidemiological Studies on Bacterial Isolates from Patients on Intensive Care Units and Other Wards at FAMC

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Richard Harris, LTC, MS (8) Facility: FAMC

(9) Dept of DCI (10) Associate Investigators Don Paine

(11) Key Words: bacterial isolates, epidemiology

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine feasibility of epidemiological typing of bacterial isolates by plasmid analysis.

(16) Technical Approach: A minilysate procedure was used for rapid extraction of several groups of clinical isolates. Whole plasmid extracts and restriction enzyme digests were compared.

(17) Progress: The technique was found to be useful in strain comparison of several species of clinical isolates. Comparisons of clusters of infections are now being performed. FY94: A comparison was made of several isolates of staphylococcus epidermidis to determine the possibilitly of penumoniae and septicemia in a patient and the plasmid analysis proved useful. We should continue these types of studies as need arises for epidemiological investigation.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 92/304A (3) Status: Completed

(4) Title: Evaluation of Serotonin (5-hydroxytryptamine), Bleeding Times, and Blood Platelets in Athymic Nude and Normal Mice

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: Ronald Jackson, Ph.D. (8) Facility: FAMC

(9) Dept of DCI (10) Associate Investigators

(11) Key Words:
serotonin
athymic nude mice

Scott Bennion COL, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAR b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 49
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine blood levels of serotonin, platelet counts, and bleeding times of three strains of athymic nude mice and compare the findings with the same parameters measured in other mouse species.

(16) Technical Approach: Mice from different strains, both heterozygous and homozygous for beige trait, were anesthetized and then bleeding times were determined after amputating a standard length of their tails. Matched groups of mice were injected with serotonin prior to tail nipping. Besides bleeding times, blood was collected, pooled, and used to determine platelet counts and serotonin levels.

(17) Progress: All mouse strains carrying the beige trait showed longer bleeding times. The XiD Bg nudes' bleeding times were the longest. In fact, one of the XiD Bg nudes never coagulated, and expired under anesthesia (For a breakdown of results see data base attached). We have not analyzed serotonin levels. These results confirmed our earlier observations that certain strains of athymic mice, e.g., those carrying beige mutation trait, are associated with bleeding problems. Serotonin injections prior to tail nipping appears to reverse this problems.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 92/306A (3) Status: Ongoing

(4) Title: Evaluation of the Blacktailed Prairie Dog Cynomys ludovicianus as a Model for Hepadnavirus Replication

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator:
Kenneth E. Sherman, MAJ, MC

(8) Facility: FAMC

(9) Dept of DCI

(10) Associate Investigators
MAJ Ron Banks
CPT Michael Quintana
Dr. Anthony Gutierrez

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:___110_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a) Test 3 Hepadnovirus for viability in prairie dog model; b) survey wild population for hepadnovirus infection.

(16) Technical Approach: (a) Lab infection with known virus; (b) Field collection and evaluation of serum and tissue for liver damage and infection.

(17) Progress: 110 subjects have been tested to date.

Publications and Presentations: None

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-300

Hepatitis C in Pregnancy: Viral Titers and Thymosin Levels

START DATE: Oct 93 EST COMP DATE: Oct 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Kenneth Sherman, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Clin Invest/Molecular Biology

ASSOCIATE INVESTIGATORS: Judith O'Brien

PERIODIC REVIEW DATE: Dec 93 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: Chiron Corp, bDNA kit; FACT PCR reagents

KEY WORDS: Hepatitis C, thymosin, pregnancy

OBJECTIVE: To evaluate the viral load during pregnancy, to try and correlate this with the level of thymosin alpha-1, a natural immunomodulatory peptide which tends to increase in the serum of women during pregnancy.

TECHNICAL APPROACH: Monthly blood specimens drawn from 10 gravid patients (who have confirmed hepatitis C infection) from the University of Colorado and other affiliated hospitals will be analyzed at FAMC. This serum will be coded and analyzed for hepatitis C by bDNA and PCR techniques.

PROGRESS:

Number of subjects enrolled to date: 5
Number of subjects enrolled for reporting period: 5
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Serial specimens being collected per protocol.

PUBLICATIONS: ?

PRESENTATIONS: ?

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-302A

Training for Animal Resources Service Personnel in Medical Surgical, and Emergency Care and Treatment, and Laboratory, Pathology, and Radiologic Procedures for Various Laboratory Animal Species

START DATE: 1 Aug 94 EST COMP DATE: 31 Jul 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Kevin Corcoran, MAJ, VC

FACILITY/DEPT/SVC: FAMC/Clin Invest/Animal Res

ASSOCIATE INVESTIGATORS: Charmaine Chase, Penelope Giese

PERIODIC REVIEW DATE: Jul 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: training, animals

OBJECTIVE: To provide training in routine and emergency medical, surgical, laboratory, pathology and radiology procedures for personnel of the Department of Clinical Investigation using government-owned animals.

TECHNICAL APPROACH: Proficiency in routine methods and animal emergencies must be developed and maintained by personnel requiring knowledge of the procedures used in working with laboratory animals. This training will enable the individual to perform tasks with expediency and efficiency and with minimal trauma to the animal.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Didactic training only to date.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-303

Laboratory Immunological Studies on Immunodeficiency, Autoimmunity, Leukemia, Lymphoma, and Breast Cancer

START DATE: Sep 94 EST COMP DATE: Indef STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Michael Lieberman, LTC, MS

FACILITY/DEPT/SVC: FAMC/Clin Invest/Immun

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: Oct 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: immunology tests

OBJECTIVE: To provide clinically relevant diagnostic and prognostic information with therapeutic implications.

TECHNICAL APPROACH: To perform immunodiagnosis, immunological classification, and clinical correlation of disorders of immunodeficiency, autoimmunity, immunoproliferation and hypersensitivity using specialized tests as requested by clinicians on a consultative basis.

PROGRESS:

Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: This protocol is an update of a previously approved, long-standing study.

PUBLICATIONS: ?

PRESENTATIONS: ?

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 91/401A (3) Status: Terminated

(4) Title: Pediatric Intubation Training Using the Ferret Model

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Beverly Anderson, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:
Brian Carter, MAJ, MC

(11) Key Words:
training
feret intubation

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_480 procedures on 19 __
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a live, realistic animal model for teaching the life-saving skills of neonatal endotracheal intubation.

(16) Technical Approach: Per protocol.

(17) Progress: Several successful training exercises have been conducted. Protocol terminated due to closing of obstetrics and the newborn nursery.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 92/402 (3) Status: Completed

(4) Title: Restandardization of Bayley Scales of Infant Development

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: (8) Facility: FAMC
Majorie Feinberg, OTR, DAC EFMP

(9) Dept of PEDS (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 30
d. Total Number of Subjects Enrolled to Date: 30
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To recruit and test 10 subjects per examiner using the updated Bayley scale of infant development as part of national restandardization effort.

(16) Technical Approach: Recruited subjects from well baby clinic. Scheduled appointments for teting. Tested subjects. Submitted test results to psychological corporation.

(17) Progress: On 21 Oct 923, MAJ Sherman expeditiously approved a minimal risk addendum to extend the study to include the restandardization of the Bayley Scales of Infant Neurodevelopmental Screen.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 22 Aug 94 (2) Protocol #: 92/405 (3) Status: Completed

(4) Title: Hypertrophic Cardiomyopathy and Disproportionate Septal Hypertrophy in Newborns

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Brian Carter, MAJ, MC (8) Facility: FAMC

(9) Dept of PEDS/Newborn (10) Associate Investigators

(11) Key Words:
newborn
cardiac hypertrophy

MAJ Steven Neish, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 7
d. Total Number of Subjects Enrolled to Date: 24
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine presence of hyperinsulinemia in macrosomic infants not born to diabetic women and assess any relationship of sach macrosomia and hyperinsulinemia with cardiac hypertrophy.

(16) Technical Approach: Cord blood analysis and newborn echocardiogram.

(17) Progress: 24 total enrolled, lab lost/discarded samples of cord blood on 6, echocardiogram not done on 6 others leaving 12 completed studies. Need to enroll and complete studies on at least 8 more subjects.

FY94: PI PCS to WRAMC. Does not wish to continue this work.

Publications and Presentations: Carter BS, McNabb F, Merenstein GB: Does Fetal Hyperinsulinemia Truly Reflect Fetal Hyperglycemia? Clin Res, vol 41(1), 1993; 69A

Presented at 1993 Western Society for Pediatric Research Meeting, Feb 19 93, Carmel, CA

Detail Summary Sheet

(1) Date: 5 Apr 94 (2) Protocol #: 92/416 (3) Status:Terminated

(4) Title: Improved Group A Strep Growth in Selective Media As an Indicator of True Infection

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Frederic Bruhn, COL, MC (8) Facility: FAMC

(9) Dept of PEDS (10) Associate Investigators Robert Wittler, MAJ, MC

(11) Key Words: group A strep

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate increased recovery of Group A beta hemolytic streptococci (GABS) on selective media (Sheep blood agar supplemented with trimethoprim-sulfamethoxazole, i.e., SBA-SXT) compared to standard media (sheep blood agar, SBA), and to correlate increased recovery of GABS with "true" infection versus a carrier state.

(16) Technical Approach: Approximately 300 patients ages 5-15 will have throat culture and venopuncture as part of this multi-institutional study.

(17) Progress: No patients entered, awaiting lab materials from the Children's hospital. No progress FY 92 and FY 93. Study completed at Children's; study terminated at FAMC where no progress was made.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Jun 94 (2) Protocol #: 92/422 (3) Status: Terminated

(4) Title: Family History of Growth and Pubertal Development in Children with Constitutional Delay

(5) Start Date: (6) Est Compl Date: 1993

(7) Principal Investigator: John Hanks, CPT, MC (8) Facility: FAMC

(9) Dept of PEDS/Adol (10) Associate Investigators Robert Slover, LTC, MC

(11) Key Words:
constitutional delay
delayed puberty

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:____230 questionnaire___
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Compare pertinent information.

(16) Technical Approach: Use of identical questionnaires in families with children with and without constitutional delay.

(17) Progress: About 1200 questionnaires given out, about 700 returned. Project is progressing well. Have been unable to locate adequate number of families with constitutionally delayed children. Would like to continue data gathering. Will be leaving FAMC July 93 for WBAMC. AI retired FY94.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 7 Jun 94 (2) Protocol #: 92/423 (3) Status: Ongoing

(4) Title: Development of a Placental Trophoblast Cell Culture for the in Vitro Study of Placental Metabolism

(5) Start Date: (6) Est Compl Date: 1997

(7) Principal Investigator:
Beverly Anderson, LTC, MC

(8) Facility: FAMC

(9) Dept of PEDS/Newborn

(10) Associate Investigators
Ron Jackson, Ph.D

Ann Anderson, MD, UCHSC
Fred Battaglia, M.D., UCHSC
Ann Anderson, MD

(11) Key Words:
tissue culture
placental trophoblast

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jun b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop an in vitro placental trophoblast culture for human placental trophoblast to study basic normal and abnormal metabolism.

(16) Technical Approach: In vitro cell culture; tracer studies with stable or radioactive isotope labelled substrates.

(17) Progress: We have made great progress in use of the choriocarcinoma cells to establish techniques and methods for study, the human placental cells are growing well and ready for study at this time, and work with the sheep placenta will be undertaken this next academic year. FY94: Progress was impeded due to staffing problems. Grant proposals are currently being prepared for continued work. Supplies and resources are currently available to re-initiate studies.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 Nov 93 (2) Protocol #: 93/400 (3) Status:Terminated

(4) Title: The Effects of Antenatal Phenobarbital Administration in High Risk Pregnancies and the Prevention of Intraventricular Hemorrhage in Premature Babies

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Una Espenkotter, CPT, MC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators
Rob Howard

(11) Key Words: phenobarbital, premature infant, high-risk preganacy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Nov b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 105
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To identify the incidence of intraventricular hemorrhage in high risk neonates before and after the antenatal use of phenobarbital.

(16) Technical Approach: A retrospective chart review of high risk neonates and the effects of antenatal phenobarbital administration in preventing intraventricular hemorrhage.

(17) Progress: Charts from 1985-1991 have been reviewed. We are currently gathering data from 1992 and 1993, at which point, our chart review will be completed. FY94: Terminated due to closure of Pediatric training program.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 93/402 (3) Status: Ongoing

(4) Title: The False Negative Rate of the Denver II in the Fitzsimons Army Medical Center Pediatric Population 7-36 Months of Age

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator:
David Burgess, DAC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators
J. Householder
C. Spicer
L. Smith

(11) Key Words:
screening
child development
Denver II

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine false negative rate of Denver II; this will allow calculation of sensitivity and specificity of the Denver II as a screening test.

(16) Technical Approach: Will test all children with normal Denver II results over a 24-month period (N=400).

(17) Progress: Study will begin 1/94. Personnel recently completed training with the Revised Bayley Scales of Infant Development which will then be used as the "gold standard". The new test was published Sept 93.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 93/403 (3) Status: Completed

(4) Title: Lead Screening for 12 Month Old Children Seen in the Pediatric Well Child Clinics at the Fitzsimons Army Medical Center

(5) Start Date: 1993 (6) Est Compl Date: 1993

(7) Principal Investigator: David Burgess, DAC (8) Facility: FAMC

(9) Dept of PEDS (10) Associate Investigators
U. Espenkotter
C. Wrubel
R. Wittler
M. Schofield

(11) Key Words:
screening
blood lead levels

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ____Jan___ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine prevalence rate of 12-month old children with increased blood lead levels at FAMC. Determine sensitivity, specificity and positive predictive value of lead screening questionnaire.

(16) Technical Approach: Compare screening questionnaire results to "gold standard" capillary blood lead level.

(17) Progress: The study was terminated earlier than anticipated due to budget cuts which eliminated the phlebotomist for this project. Children 182; LQ 164 (90%); BLL 134 (74%); LQ/BLL 122 (67%); True Positives 3 (2%;3/134).

Publications and Presentations: Screening for lead posioning at the FAMC. Presented: Howard Johnson Award, 1993.

An abstract was accepted for presentation at the Western Society for Pediatric Research, 12 Feb 94, Carmel, CA.

Detail Summary Sheet

(1) Date: 5 Apr 94 (2) Protocol #: 93/417 (3) Status: Ongoing

(4) Title: Identification of Family Strengths and Needs Using the Q-Sort Process

(5) Start Date: 1993 (6) Est Compl Date: 1995

(7) Principal Investigator: Marjorie Feinberg, DAC (8) Facility: FAMC

(9) Dept of PEDS (10) Associate Investigators

(11) Key Words: MAJ Pat Chandler

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 23
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine what families perceive as important supports during babies' hospitalization.

(16) Technical Approach: Parent interview and demonstration of Q-Sort Process to prioritize needs of family.

(17) Progress: 23 families whose babies meet the criteria for part II eligibility have been interviewed. A total of 40 families is our goal. Completion data is dependent on census in NICU which has been low in the past 2 months. We feel it will take another year to complete the interviews depending on census in NICU. Study is still in progress.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/420A (3) Status: Completed

(4) Title: Adjuvant Therapy with Interferon-gamma for Group B Streptococcal Sepsis in Neonatal Rats

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Robert R. Wittler, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDIATRICS

(10) Associate Investigators
Richard W. Harris, Ph.D.
Don Paine, BS
Sgt Burgess

(11) Key Words:
group b streptococcus
interferon-gamma
neonatal rats

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____26_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if interferon-gamma in conjunction with penicillin has a beneficial effect on the mortality resulting from group B streptococcal (GBS) sepsis in a neonatal rat model.

(16) Technical Approach: Neonatal rats (48-72 hrs of age) are infected with $1x10^5$ cfu GBS SC. Pups were randomized to four treatment groups: Controls, IFN-gamma, Penicillin, or Penicillin plus INF-gamma. Quantitative blood cultures were obtained at 18 hrs and 42 hrs after infection. Mortality is assessed over a 5 day period.

(17) Progress: The pilot phase of the study was used to develop technical skills, the proper inoculum of GBS, and the proper timing of penicillin administration to achieve a goal of 50-75% mortality in the penicillin (no IFN-8) treatment group. That goal was accomplished with a GBS inoculum of 10^5 cfu and administration of penicillin beginning 18 hours post infection. Results of the study phase protocol revealed no significant difference in mortality between treatment groups as dertermined by survival analysis (actuarial method and log-normal regression model) and by contingency table analysis.

Publications and Presentations: None

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-400

Felbamate Monotherapy in Newly Diagnosed Partial Epilepsy

START DATE: Feb 94 EST COMP DATE: Feb 95 STATUS: Pending

PRINCIPAL INVESTIGATOR: Brian Ryals, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Ped/Ped Neur

ASSOCIATE INVESTIGATORS: Frederic Bruhn, COL, MC, Michael Coats, LTC, MC

PERIODIC REVIEW DATE: Jan 94 REVIEW RESULTS: Continue
FUNDING: FACT
GIFTS: Wallace Laboratories, prepackaged drug and placebo

KEY WORDS: epilepsy, felbamate, IND

OBJECTIVE: To determine the efficacy and safety of two dosages of felbamate monotherapy in comparison to placebo in preventing recurrent seizures in subjects with newly diagnosed partial-onset epileptic seizures.

TECHNICAL APPROACH: Approximately 15 patients will be enrolled at FAMC. Eligible patients will be between 14 and 65 years of age will be randomized to felbamate 1200 mg/day, felbamate 2400 mg/day or placebo. The 1200 mg group will begin 1200 mg on the first day of the 52-week treatment period. The 2400 mg group will be titrated to 2400 mg over a 2-week period.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: FDA and Wallace Laboratories have suspended use of the drug.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-401

Open-Label, Follow-On Felbamate Therapy in Adult Subjects with Newly Diagnosed Partial Epilepsy

START DATE: NA EST COMP DATE: NA STATUS: Terminated

PRINCIPAL INVESTIGATOR: Brian Ryals, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Ped/Ped Neur

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: Feb 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: NA

OBJECTIVE: NA

TECHNICAL APPROACH: NA

PROGRESS:
Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: After the IRC reviewed and approved this IND protocol, the PI decided he didn't want to participate.

PUBLICATIONS: None

PRESENTATIONS: None

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-402

Use of a Degenerate, Nested Primer PCR Technique for Non-Invasive Detection of Anogenital Human Papillomavirus in Males

START DATE: Mar 94 EST COMP DATE: May 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Anthony Gutierrez, PhD, DAC

FACILITY/DEPT/SVC: FAMC/Ped/Clin Invest/Adol Med

ASSOCIATE INVESTIGATORS: Clive Daniels, CAPT, USAF, MC, Judy O'Brien, BS

PERIODIC REVIEW DATE: Apr 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: human papillomavirus, PCR

OBJECTIVE: To determine the sensitivity and reproducibility of the degenerate, nested primer PCR technique for non-invasive detection of anogenital human papillomavirus in males.

TECHNICAL APPROACH: To collect swabbed epithelial specimens from 10 adult male subjects diagnosed with anogenital condylomata and study using PCR.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: PCR primers designed. Primers synthesized. PCR optimized with positive results. Protocol approved at San Diego Naval Medical center 9/15/94.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PEDIATRIC ONCOLOGY GROUP PROTOCOLS

Pediatric Oncology Group Protocols.

82/403 POG 7799	92/400 POG 9151	93/404 POG 9047
82/414 POG 8158	92/401 POG 9153	93/405 POG 9048
87/404 POG 8654	92/403 POG 9150	93/406 POG 9049
90/408 POG 8823/24	92/404 POG 9152	93/407 POG 9130
90/410 POG 8829	92/406 POG 9031	93/408 POG 9239
90/412 POG 8850	92/407 POG 9135	93/409 POG 9227
90/414 POG 8828	92/408 POG 9136	93/411 POG 9219
90/415 POG 8650	92/412 POG 9132	93/412 POG 9244
91/406 POG 9000	92/414 POG 9259	93/413 POG 9262
91/407 POG 9005	92/420 POG 9233/34	93/414 POG 8935
91/408 POG 9006	92/421 POG 9243	93/416 POG 9170
91/409 POG 9046	93/401 POG 9226	93/418 POG 9264
		93/419 POG 9317

START DATE: 1982 EST COMP DATE: 1994 STATUS: Terminated

PRINCIPAL INVESTIGATOR: Brian Carter, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Ped

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: 4 Oct 94 REVIEW RESULTS: Terminated
FUNDING: NA
GIFTS: NA

KEY WORDS: NA

OBJECTIVE: Cancer treatment.

TECHNICAL APPROACH: Per NCI protocol.

PROGRESS:

Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor: NA

Summary of prior and current progress: None. Protocols terminated due to elimination of the pediatric oncologist position, reduction of pediatric staff and limitation in pediatric patient population at FAMC.

PUBLICATIONS: None. PRESENTATIONS: None.

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 93/475 (3) Status: Ongoing

(4) Title: Clinical Comparability of Two Once-Daily Forms of Diltiazem: Effect of Substitution on Blood Pressure Control

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Lea Conyers, DAC

(8) Facility: FAMC

(9) Dept of Pharmacy

(10) Associate Investigators
MAJ John Grabenstein
LTC Roger Potyk
MAJ Lisa Johnson

(11) Key Words:
Diltiazem, hypertension, comparability

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:____Sep___ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____17_____
d. Total Number of Subjects Enrolled to Date:_____17_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To assess the comparability of clinical effects of Cardizem and Dilacor in the treatment of hypertension.

(16) Technical Approach: Multicenter retrospective analysis of patient records.

(17) Progress: None, recently approved.

FY94: Seventeen patient records reviewed at Ft. Riley this FY. Anticipate completion of study in 1995.

Publications and Presentations: None

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-500

Relative Efficacy of the Halstead-Reitan Neuropsychological Test Battery as Compared to Tests of Executive Control System function in Determining Extent and Nature of Brain Dysfunction in Active Duty Soldiers Referred for Neuropsychological Assessment

START DATE: Dec 93 EST COMP DATE: Sep 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Donald Taylor, Ph.D., DVAMC

FACILITY/DEPT/SVC: FAMC/Psychiatry/Psychology

ASSOCIATE INVESTIGATORS: Richard Sherman, LTC, MS, Bryan Smith, Psy.D.

PERIODIC REVIEW DATE: Dec 93 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: neuropsychological assessment

OBJECTIVE: As per title.

TECHNICAL APPROACH: Forty soldiers without psychiatric or neurologic conditions will be administered a multitude of neuropsychological tests. Two experimental groups of 40 soldiers each administered the identical battery of tests will be studied. One of the experimental groups will be referred for testing subsequent to closed head injury. The other 40 will consist of soldiers with miscellaneous other disorders who are suspected of brain impairment and have been referred for neuropsychological assessment.

PROGRESS:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Medical Hold Company personnel have been approached x3 for volunteering for study. Result=0 volunteers. Attempted grant to pay volunteers. Grant rejected.

PUBLICATIONS: None.

PRESENTATIONS: None.

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 80/602 (3) Status: Ongoing

(4) Title: I.V. Administration of 131-I-6-B Iodomethylnorcholesterol (NP-59) for Adrenal Evaluation and Imaging

(5) Start Date: 1980 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Mike McBiles, LTC, MC (8) Facility: FAMC

(9) Dept of Radiology/Nuc.Med. (10) Associate Investigators

(11) Key Words:
adosterone
adrenal glands

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jul b. Review Results: Ongoing
c . Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 35
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Clinical evaluation of NP-59 as a diagnostic agent for the detection of adrenal cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

(16) Technical Approach: Each patient will be studied while taking Lugol's or SSKI to protect thyroid. Some patients will have adrenal function suppressed with Dexamethasone. Following a 2 millicurie dose of NP-59, each patient will be scanned at day 3 and possibly day 5 and 7.

(17) Progress: The total number of patients entered into the study at all sites from its start in 1978 thru 1 May 94 is 81. Two subjects were enrolled this annual report period; 1 at FAMC and 1 at WBAMC. Acceptable images of the adrenal glands were obtained in all patients completing the study. The results of all 81 patients imaged since the onsent of this protocol have provided useful clinical information. In our experience, the drug has proved both safe and efficacious. Further patient studies will continue to be performed. The protocol is still under the IND process which requires maintenance of the protocol for use.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 May 94 (2) Protocol #: 93/601 (3) Status: Terminated

(4) Title: Comparison of Three Quality Control Methods Used in the Preparation of Tc-99m Exametazine (Ceretec)

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Grant Morgan, MAJ, MC (8) Facility: FAMC

(9) Dept of RADIOLOGY (10) Associate Investigators

(11) Key Words: Richard E. Stotler, LTC, MS

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___May____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To assess two methods of quality control testing for practical use within the Nuclear Medicine Service and demonstrate the validity of these methods using a dose calibrator system common to all Nuclear Pharmacy Hot Labs.

(16) Technical Approach: Per protocol.

(17) Progress: New study. FY94: Study terminated because PI PCS'd.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 2 Aug 94 (2) Protocol #: 93/602 (3) Status: Ongoing

(4) Title: A Prospective Evaluation of Technetium^{99m} Sestamibi in the Detection of Breast Cancer

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Marc Cote, MAJ, MC

(8) Facility: FAMC

(9) Dept of RADIOLOGY/Nuc Med

(10) Associate Investigators
Mike McBiles, LTC, MC
Gloria Komppa, M.D.
Thomas Verdon, COL, MC
Sharon Hammond, MAJ, MC
Phillip Mallory, LTC,
Richard Stotler, LTC, MS
Cathy Parsells, MAJ, MC
Bruce Hamilton, LTC, MS

(11) Key Words:
Technetium 99m, sestamibi
breast, cancer

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___Aug____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period: ____2_____
d. Total Number of Subjects Enrolled to Date: _____2_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To find an imaging modality that can help differentiate cancer from benign lumps or fibrocystic changes seen on mammography.

(16) Technical Approach: SPECT and planar nuclear imaging of women with breast lumps having biopsies will be imaged.

(17) Progress: FY94: Study was held up pending request for H. Jackson Funding. We will submit a request to the IRB to update the protocol to new findings recently announced at national meeting in May 1994 before we proceed any further.

Publications and Presentations: None

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-600

Protocol for Evaluation of Cedars-Sinai and Emory Algorithm for Analysis of Myocardial Tc99m Sestamibi Tomographs

START DATE: Nov 93 EST COMP DATE: Indef STATUS: Terminated

PRINCIPAL INVESTIGATOR: Mike McBiles, LTC, MC

FACILITY/DEPT/SVC: FAMC/Rad/Nuc Med

ASSOCIATE INVESTIGATORS: None.

PERIODIC REVIEW DATE: Nov 93 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: sestamibi, algorithm

OBJECTIVE: To validate the Cedars-Sinai and Emory algorithm.

TECHNICAL APPROACH: Two computer programs will be applied to routine scans which are performed for diagnostic purposes to determine the validity of the new image processing and display algorithms as compared to the standard of practice.

PROGRESS:

Number of subjects enrolled to date: 5
Number of subjects enrolled for reporting period: 5
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Terminated.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-601

Gadolinium Enhanced MRI in the Detection of Breast Disease in High Risk Women with Altered Parenchymal Pattern

START DATE: Apr 94 EST COMP DATE: Mar 97 STATUS: Terminated

PRINCIPAL INVESTIGATOR: J. Michael Smith, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Rad/MRI

ASSOCIATE INVESTIGATORS: John Evans, MD, Kevin Rak, MD, Tom Maroldo, MD

PERIODIC REVIEW DATE: Dec 93 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: MRI, gadolinium, breast disease

OBJECTIVE: MRI is more sensitive and specific in detecting carcinoma in the altered beast and can be effective adjunct to diagnosis when applied to selective population groups.

TECHNICAL APPROACH: A prospective analysis will be performed on enhancing lesions based on the following characteristics: time of contrast enhancement, early enhancement (<3 min), late enhancement (>3 min); pattern of enhancement, focal or diffuse, irregular or well-circumscribed. 100 women with a current screening population of approximately 8-10,000.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Terminated.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-602

Use of Indium-111 Pentetreotide in Patients with Known or Suspected Neuroendocrine Tumors Containing Somatostatin Receptors

START DATE: Apr 94 EST COMP DATE: Indefinite STATUS: Completed

PRINCIPAL INVESTIGATOR: Albert Lambert, MAJ, MC

FACILITY/DEPT/SVC: FAMC/Rad/Nuc Med

ASSOCIATE INVESTIGATORS: Mike McBiles, LTC, MC, Mike McDermott, COL, MC, Daniel Tell, COL, MC, Sharon Hammond, MAJ, MC, David Greco, CPT, MC

PERIODIC REVIEW DATE: Mar 94 REVIEW RESULTS: Completed
FUNDING: NA
GIFTS: Mallinckrodt Medical Inc., IND drug

KEY WORDS: neuroendocrine tumor, somatostatin receptors, Indium-111

OBJECTIVE: To improve diagnostic scans in patients on whom conventional imaging methods are ineffective or insufficient.

TECHNICAL APPROACH: Indium in-111 pentetreotide at a dose of 6.0 mCi (222 MBq) administered by IV push. Scans will be obtained 4, 23, and 48 hours after injection. Approximately 10 subjects referred from Endocrinology, Hematology/Oncology and Surgery Services at FAMC will be included in the study.

PROGRESS:

Number of subjects enrolled to date: 6
Number of subjects enrolled for reporting period: 6
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: In-111 OctreoScan received FDA approval 15 Jun 94. Six patients were involved in the study. No adverse effects were noted. The study did not change the clinical management in any patient.

PUBLICATIONS: None.

PRESENTATIONS: None.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 91/650A (3) Status: Terminated

(4) Title: Study of Hemoglobin and Red Cell Metabolism in Didelphis marsupials

(5) Start Date: 1993 (6) Est Compl Date: Indifinite

(7) Principal Investigator: N.C. Bethlenfalvay, MD (8) Facility: FAMC

(9) Dept/Svc: Primary Care (10) Associate Investigators: J.E. Lima, DAC

(11) Key Words:
D. Virginiana/marsupialis
purine (deoxy) nucleotide
metbolism

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To compare red cell purine (deoxy) nucleotide content, synthesis and catabolism in these cells with those of D. virginiana and of human erythrocytes on record.

(16) Technical Approach: Per protocol.

(17) Progress: No animals have been received at time of review. Because of the difficulties in procuring the study animals from Panama, the ILACUC approved the protocol to continue, but under new work unit number 93/650A, stating that it was no fault of the investigator that no progress had been made.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 2 Aug 94 (2) Protocol #: 92/650 (3) Status: Ongoing

(4) Title: Patient Education Through Record Sharing

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator:
Stuart Smith, M.D., DAC

(8) Facility: FAMC

(9) Dept of PCCM

(10) Associate Investigators

(11) Key Words:
patient education
record sharing

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Aug b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 19
d. Total Number of Subjects Enrolled to Date: 54
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the role of patients in cost/quality.

(16) Technical Approach: Partial record sharing.

(17) Progress: To date 35 patients have participate and 30 have completed the initial steps. Ten have completed all steps and 20 mailings went out in Aug 93. FY94: Preliminary information suggests our patients do not know their problems as well as they could.

Publications and Presentations: Three papers are in the process of preparation. A poster presentation was accepted for the 15th Annual Conference on Patient Education sponsored by the American Academy of Family Physicians and the Society for Teachers of Family Medicine, Nov 18-21, 1993, at Scottsdale, AZ, and at the same meeting held in Nov 94.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/650A (3) Status: Ongoing

(4) Title: Study of Hemoglobin and Red Cell Metabolism in Didelphis marsupials

(5) Start Date: 1993 (6) Est Compl Date: Indefinite

(7) Principal Investigator: N.C. Bethlenfalvay, MD (8) Facility: FAMC

(9) Dept/Svc: Primary Care (10) Associate Investigators: J.E. Lima, DAC

(11) Key Words:
D. Virginiana/marsupialis
purine (deoxy) nucleotide
metbolism

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____2_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To compare red cell purine (deoxy) nucleotide content, synthesis and catabolism in these cells with those of D. virginiana and of human erythrocytes on record.

(16) Technical Approach: Purine (deoxy) nucleotides and activities of adenosine deaminase, deoxyadenosine kinase, (d) AMP deaminase, S-adenosylhomocysteine hydrolase, S-AMP synthetase, will be studied in intact and lysed red cells and spleen extract, by HPLC/liquid radiochromatography.

(17) Progress: Like red cells of D. virginiana, but unlike human erythrocytes D. marsupialis red cells have a high activity deoxyAMP deaminase. S-adnosylhomocysteine hydrolase activity is low in ADA deficient tissues, but high in ADA sufficient tissues.

Publications and Presentations: Four papers in preparation.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-650

Impact of Patient Carried Records on the Health Care of Active Duty Service Women

START DATE: Sep 94 EST COMP DATE: Sep 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Stuart Smith, MD, DAC

FACILITY/DEPT/SVC: FAMC/Primary Care/Community Med

ASSOCIATE INVESTIGATORS: Thomas Frederikesen-Cherry, MD, J. Powell Data, MS, C. Hanson, LTC, MS

PERIODIC REVIEW DATE: May 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: health care delivery, patient records

OBJECTIVE: To determine the effect of patient oriented, abstracted patient records.

TECHNICAL APPROACH: Subjects will be 200 women ages 18 to 62 who are patients at FAMC in both primary care and managed care systems randomly assigned to treatment and control groups.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: The focus of this work, impact of patient carried records on the health care of active duty servicewomen, was present to the Defense Women's Health Research Program on June 10, 1994. It was subsequently denied funding. Phase I of this project is ongoing in Sep 94. Phase II is being restructured for action at FAMC.

PUBLICATIONS: ?

PRESENTATIONS: ?

Detail Summary Sheet

(1) Date: 7 June 94 (2) Protocol #: 91/702 (3) Status: Ongoing

(4) Title: Effects of a Policy for Managing Children's Pain

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator: Christine Krimbill, LTC, AN

(8) Facility: FAMC

(9) Dept/Svc: Nursing

(10) Associate Investigators: Cathy Chess, MAJ, AN Monique Laflamme, LT, AN Jeff Jones, MAJ, AN

(11) Key Words: pain assessment

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: June b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To examine the effects of implementing a policy for pain assessment and management on pain related outcomes.

(16) Technical Approach: A quasi experimental design guides this study. The experimental gropu will receive training and material to implement the pain management program. On multiple occasions the following dependent variables will be measured: provider attitudes about pain, provider behaviors related to pain, pain related patient-centered outcomes, and cost factors related to recovery.

(17) Progress: The pilot study has been completed and the preliminary data analyzed. The data indicates that some modification to the Child Pain Scale needs to occur prior to the implementation of the tool in the funded 5 year study. Evaluation of this tool indicated most nurses thought it contained relevant content but it was too lengthy, complex, and cumbersome to use in its current form.

The Pain Experience History forms were felt by the nurses to be excellent but the information obtained may need to be transferred to forms at the bedside.

The Poker Chip Tool was felt to be easy to use and easy to obtain valid information on the child's pain but there was concern about giving the tool to the child at the same time that the parent evaluated the child's pain using the tool. Perhaps the child would feel the nurse did not believe the child's assessment of their own pain. Orientation to the tools and program was felt to be appropriate in

time and content but more support during their study for questions/problems may be needed.

The Pain Flow Sheet was assessed to be positive but amy also need some minor changes to make the form easier and faster to use.

Although the collection of data for the pilot study has been completed, the Child Pain Scale is being revised and we request that the study be continued to allow for retesting of this tool here. There is minimal risk associated with this tool as it measures a child's behavioral responses to pain and involves mostly observation.

FY94: Originally entitled "Pilot Study for Psychometric Properties of Selected Tools for Pain Assessment and Management in Children". The full proposal was reviewed and approved by the IRC on 7 Dec 93 with the new title as above.

Baseline data collection was completed at the end of Nov 94, and data analysis for this phase is in progress. Review of the data suggests that the tools for measuring pain are meeting the standards set for reliability. Preliminary findings on child and parent satisfaction with pain management suggests that while in the hospital children and parents are more satisfied with nurse than physician management. Telephone interviews reveal that many parents receive little if any information about addressing pain following hospitalization.

The intervention phase which commenced Dec 93 involved five mandatory 30-min educational sessions: (a) Overview of the Pain Management Protocol. (b) Gate Control Theory and Nonpharmacologic Intervetnions, (c) Pharmacologic Interventions, (d) Observation Assessment Tool, and (e) Poker Chip Tool and Pain Unit staff could attend a class held on the unit or watch the videotape of that class. Implementation will end 31 May 94, and a 6-mo maintenance phase will begin 1 Jun 94. Interestingly, preliminary results of the implentation phase are in congruence wtih the theory of diffusion of innovations (Rogers, 1983). Personnel on the pediatric unit have demonstrated activities across the five states of diffusion: Awareness, Persuasion, Decision, Implementation, and Re-invention. Results of the baseline and implementation phase will be available upon completion of data analysis.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 93/700 (3) Status: Ongoing

(4) Title: A Pilot Survey of Timing and Utilization of Preventive Examinations at Fitzsimons Army Medical Center

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Paula Nelson-Marten, LTC, AN

(8) Facility: FAMC

(9) Dept of NURSING

(10) Associate Investigators
James Hanley, COL, MC
Janet Wilson, CPT, AN

(11) Key Words:
preventive examinations

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1114
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of this pilot study is the assessment of current utilization of preventive evaluations by active duty and retired beneficiaries of FAMC and members of the 5502d USAR as recommended by ACT, CTF, UsPSTF and ACS guidelines. A secondary purpose is to identify the usefulness of the Health Maintenance Survey in identifying the timing and utilization of preventive evaluations.

(16) Technical Approach: Per protocol.

(17) Progress: Enrollment is complete with 1114 to date. Statistical analysis is underway. Anticipate presentation of data at a meeting in the summer of 1994, and possible submission for publication.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 93/701 (3) Status: Completed

(4) Title: Advanced Practice Nursing Impact on Patients and Staff

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Wynona Stephens, LTC, AN

(8) Facility: FAMC

(9) Dept of NURSING

(10) Associate Investigators
LTC Mucha
Dr. Sherman
CPT Gaylord
CPT Boucher
LTC E. Smith
Mr. Pearce
Carolyn Jolitz, MAJ, AN

(11) Key Words:
advanced practice nursing

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jun b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 700
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the impact of the health-care delivery system of advanced practice nursing groups of the quality of patient care and staff work satisfaction.

(16) Technical Approach: (a) INdex of work satisifaction (stamps and piedmonte) administered every 6 months to all DOA personnel; (b) Structured interviews conducted every three months with key personnel; (c) Pertinent indicators monitored monthly, as med errors, falls, patient representative reports.

(17) Progress: Index of work satisfaction computeriezed and copied for 6 Oct 93 distribution; structured interviews conducted as scheduled; indicators monitored monthly. FY94: Data collection completed, manuscript in process.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 93/702 (3) Status: Completed

(4) Title: Hospitals as Teaching Sites: Converging Theory and Practice Through Clinical Application Programs Based Upon Adult Learning Concepts.

(5) Start Date: 1993 (6) Est Compl Date: Dec 1993

(7) Principal Investigator: (8) Facility: FAMC
Wynona Stephens, LTC, AN

(9) Dept of NURSING (10) Associate Investigators

(11) Key Words:
clinical applications

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jun b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the perceived effectiveness of clinical application programs such as preceptorships as a teaching strategy, particularly as a means of achieving principles of adult learning and to determine the influence of variable upon the clinical application experience particularly those inherent to program within hospitals functioning as teaching sites.

(16) Technical Approach: Computerizes survey to be administered to all 66Js in DON; survey findings to be related to theoretical framework and other areas of literature review.

(17) Progress: Proposal revised to include all 66Js, not just those arrived in last 12 months; survey revised-tailored more to military audience, with more andrological base; Vanderbilt committee suggested title change; All changes minor and does not change study intent and will be submitted to DCI after Vanderbilt University IRB approves.

FY94: Results indicated the Army Nurse Coprs Preceptorship is indeed perceived as a valid clinical application teaching strategy which promotes principles of andragogy, plus socialization and integration, into the corps.

Publications and Presentations: None

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-700

A Comparison of Initial Success Rates for Student Registered Nurse Anesthetists Performing Oral Endotracheal Intubation with the Miller Blade versus the Macintosh Blade

START DATE: May 94 EST COMP DATE: May 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Michael Fitzgibbons, 1LT, AN

FACILITY/DEPT/SVC: FAMC/Nursing/Anesth

ASSOCIATE INVESTIGATORS: Deborah Selber, CPT, AN, Barry Vance, CPT, AN

PERIODIC REVIEW DATE: May 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: intubation training

OBJECTIVE: To determine if there is a difference in success rate for the first 50 adult oral endotracheal intubations performed by novice SRNAs using a Miller blade vs the first 50 adult oral endotracheal intubations performed by novice SRNAs using a Macintosh blade.

TECHNICAL APPROACH: Ten novices will be studied at FAMC. Evans ACH will also be used as an additional study site.

PROGRESS:

Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Study ongoing.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-701

Identifying Process Variations Via Risk-Adjusted Outcome

START DATE: Oct 94 EST COMP DATE: Oct 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Kathyrn Dolter, MAJ, AN

FACILITY/DEPT/SVC: FAMC/Nursing/Research

ASSOCIATE INVESTIGATORS: Elizabeth Hill, MAJ, AN

PERIODIC REVIEW DATE: Sep 94 REVIEW RESULTS: Approved
FUNDING: Tri-Service Grant
GIFTS: NA

KEY WORDS: practice impact, quality of care

OBJECTIVE: To assess the validity of using risk-adjusted mortality as a screening mechanism to identify variations in practice impacting on quality of care.

TECHNICAL APPROACH: This multi-center study will utilize a combination case control and exploratory descriptive design to assess input, process, and outcome variables of the coronary artery bypass graft surgery patient care process.

PROGRESS:
Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: None. Study recently approved at FAMC.

PUBLICATIONS: NA

PRESENTATIONS: NA

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-702

Relationship of Posttetanic Count and Train of Four Response During Deep Neuromuscular Blockade Using Vecuronium Bromide

START DATE: Oct 94 EST COMP DATE: Oct 95 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Burton Stover, CPT, AN

FACILITY/DEPT/SVC: FAMC/Nursing/Anesth

ASSOCIATE INVESTIGATORS: Therese Conner, MAJ, AN, George Altmann, CPT, AN

PERIODIC REVIEW DATE: Oct 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: neuromuscular blockade

OBJECTIVE: To describe the relationship between the posttetanic count and the time to the return of the initial response to TOF stimulation when using tactile evaluation of the surgical patient receiving vecuronium bromide.

TECHNICAL APPROACH: A descriptive study design will be utilized to quantify the relationship between PTC and the time interval to the return of first response to TOF stimulation.

PROGRESS:
Number of subjects enrolled to date: NA
Number of subjects enrolled for reporting period: NA
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: None. Recently approved study.

PUBLICATIONS: NA

PRESENTATIONS: NA

Detail Summary Sheet

(1) Date: 7 Jun 94 (2) Protocol #: 93/750 (3) Status: Ongoing

(4) Title: Inter-Examiner Reliability of the Trigger Point Examination in Myofascial Pain Syndrome

(5) Start Date: 1993 (6) Est Compl Date: 12/93

(7) Principal Investigator:
Steven Shannon, MAJ, MC

(8) Facility: FAMC

(9) Dept of Physical Medicine

(10) Associate Investigators
Dr. Robert Gerwin, MD
Dr. C.Z. Hong, MD
Dr. David Hubbard, MD

(11) Key Words:
trigger points
myofacial pain
inter-examiner reliability

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jun b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 25
d. Total Number of Subjects Enrolled to Date: 25
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To see if four experienced examiners can obtain similar physical examination data when examining for myofascial trigger point characteristics.

(16) Technical Approach: Four physicians will each sequentially examine a series of subjects, male and female, age 18 years and older in groups of 8-10 at a time randomized by a latin square design.

(17) Progress: Most of statistical anlaysis completed, but some aspects being looked at more closely. First half of paper is in rough draft form.

Publications and Presentations: None

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-760

Prospective Evaluation of Health-Care Workers Exposed To the Blood of Patients Infected with Human Immunodeficiency Virus

START DATE: Mar 94 EST COMP DATE: Mar 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Clement Hanson, LTC, MC

FACILITY/DEPT/SVC: FAMC/Clin Svc/Prev Med

ASSOCIATE INVESTIGATORS: SSGT Danny Bishop

PERIODIC REVIEW DATE: Mar 94 REVIEW RESULTS: Continue
FUNDING: NIH/CDC
GIFTS: NA

KEY WORDS: HIV, natural history, data bank

OBJECTIVE: 1) To estimate the risk of HIV infection in health-care workers (HCWs) exposed via the percutaneous, mucus-membrane, or skin route to HIV infected blood, according to type of exposure.
2) To describe the type of devices and the circumstances of the exposures sustained by HCWs.
3) To describe the clinical natural history and development of laboratory markers of HIV infected HCWs enrolled in this project who seroconvert to HIV.
4) To describe the use of post-exposure chemoprophylaxis by HCWs exposed to HIV infected blood.

TECHNICAL APPROACH: Patients will be tested for HIV within 30 days of exposure and asked to complete a questionnaire regarding the exposure ("needlestick") and also to answer personal sexual questions. The HIV testing and questionnaire will be repeated at intervals during the 12 months of the study.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: No patients or FAMC personnel enrolled to date in this study. Although needlesticks occur every month at FAMC, there have been no instances reported to Preventive Medicine of a known occupational (needlestick, sharps stick, nucous membrane exposure) exposure to an HIV-infected patient.

PUBLICATIONS: None. PRESENTATIONS: None.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 91/800A (3) Status: Terminated

(4) Title: Survey of Tick Vectors and Wild Rodents for the Presence of Borrelia burgdorferi in the Deer Tick, Ixodes pacificus, and in the Black-legged Tick, Ixodes scapularis

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator: Lester Hale, Ph.D. (8) Facility: FAMC

(9) Dept/Svc: USA Environ.Hyg. (10) Associate Investigators: Michael Quintana, CPT, MS; William E. Irwin, DAC; Frederick J. Harrison, Jr., DAC

(11) Key Words: Lyme disease

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____857_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To survey wild rodent populations for tick vectors of the Ixodes species and to determine if Borrelia burgdorferi is present in these vectorrs.

(16) Technical Approach: Per protocol.

(17) Progress: Lyme Disease risk assessments have been made at 15 installations, with Borrelia burgdorferi isolated from Tamias spp. and Ixodes ticks at Camp Ripley, WI. Borrelia burgdorferi was also identified in Ixodes pacificus at Camp Pendleton, CA. This protocol will expire in June 94 and will be rewritten and submitted for a new review.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 91/801A (3) Status: Terminated

(4) Title: Studies of the Metabolic Adaptation in Response to Chronic Severe Hypoxia in the Pregnant Sheep

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator: Matthew Schofield, CPT, MS (8) Facility: UC Perinatal Research Facility located at FAMC

(9) Dept/Svc: DCI/Biochem. (10) Associate Investigators: Frederick Battaglia, MD

(11) Key Words:
hypoxia
metabolic adaptations

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To study the metabolic adaptations which occur under chronic hypoxia. The experimental design tests the hypothesis that a key factor in maintaining viability during severe chronic hypoxia is the ability of the fetus to metabolize lactate for production of non-essential amino acids, that are, in turn, metabolized by the placenta.

(16) Technical Approach: Chronic hypoxia in the fetal sheep is created (125-130 d. gestation) by means of a balloon occluder placed around the common internal iliac in a chronically catheterized pregnant ewe. Isotope labelled substrates are used to measure metabolism and transport of metabolites.

(17) Progress: Study was submitted for MRDC funding, although funding was announced this past summer, no funds were forwarded to FAMC. Study was not funded in FY 94. Some pilot assay work was performed on samples provided by UCHSC.

Publications and Presentations: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-800A

Surveillance of Rodent Populations for Hantavirus

START DATE: Mar 94 EST COMP DATE: Indefinite STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Michael Quintana, CPT, MS

FACILITY/DEPT/SVC: FAMC/USAEHA-W/Entomological Sciences

ASSOCIATE INVESTIGATORS: Thomas Gargan, MAJ, MS, Lester Hale, PhD, William Irwin, Frederick Harrison, Jr.

PERIODIC REVIEW DATE: Feb 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: Hantavirus, surveillance

OBJECTIVE: To assess the health threat to the military communities within the USAAEHA-W support area posed by hantavirus.

TECHNICAL APPROACH: Field study. Approved technologies and techniques will be used to capture rodent species know to be infected with the hantavirus organism. Blood samples will be drawn from the tail while the animal is under anesthesia to determine if the rodent is infected. All animals that are negative for hantavirus will be returned to the area where they were trapped.

PROGRESS:

Number of subjects enrolled to date: 300
Number of subjects enrolled for reporting period: 300
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None

Summary of prior and current progress: Three surveys completed to date, 3 more survey scheduled for remainder of current year.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-801A

Survey of Tick Vectors and Wild Rodents for the Presence of Borrelia burgdorferi, in the Black-legged Tick, Ixodes scapularis and in the Western Black-legged Tick, Ixodes pacificus with Special Emphasis on Tick Vectors Attached to Various Species of Peromyscus and Neotoma

START DATE: May 94 EST COMP DATE: Indef. STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Lester Hale, PhD, DAC

FACILITY/DEPT/SVC: FAMC/USAEHA-W/Entomol

ASSOCIATE INVESTIGATORS: Michael Quintana, CPT, MS, Thomas Gargan, II, MAJ, MS, William Irwin, DAC, Frederick Harrison, Jr., DAC

PERIODIC REVIEW DATE: May 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: tick vectors, wild rodents, Lyme disease

OBJECTIVE: As per title to determined the health threat posed to the military community within the USAEHA-W support area. To make assessments, both known and suspected rodent reservoirs will be surveyed for the Lyme disease.

TECHNICAL APPROACH: Rodents will be trapped for collection of ticks, ear biopsies, and vital statistics and returned to a site near where they were trapped. Tick drags will supplement the animal data.

PROGRESS:

Number of subjects enrolled to date: 150
Number of subjects enrolled for reporting period: 150
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: One Lyme disease risk assessment was conducted at Camp Grafton, North Dakota, 27 June - 1 July 1994. A total of 33 rodents processed.

PUBLICATIONS: None.

PRESENTATIONS: None.

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 89/900 (3) Status: Ongoing

(4) Title: Evaluation of a Phase I Coxiella burnetii Vaccine (IND 610) for Immunization Against Q Fever

(5) Start Date: Unknown (6) Est Compl Date: Ongoing

(7) Principal Investigator:
Gerald G. Mindrum, COL, MC

(8) Facility: FAMC
US Army Health Clinics
Dugway Proving Grounds
Dugway, Utah 84022

(9) Dept/Svc:

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 43
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 89/901 (3) Status: Ongoing

(4) Title: Continued Evaluation of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, TC-83 Live, Attenuated, NDBR-102, Lot 4 in At-Risk Personnel IND 142

(5) Start Date: Unknown (6) Est Compl Date: Ongoing

(7) Principal Investigator: Gerald G. Mindrum, COL, MC (8) Facility: FAMC US Army Health Clinic, DPG

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 43
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 89/902 (3) Status: Ongoing

(4) Title: Evaluation of New Lots of Tularemia Vaccine, Protocol B: Comparative Assessment of Francisella tularensis Vaccine, Live, NDBR 101, IND 157

(5) Start Date: Unknown (6) Est Compl Date: Ongoing

(7) Principal Investigator: Gerald G. Mindrum, COL, MC (8) Facility: FAMC Dugway Proving Grounds US Army Health Clinic

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 43
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Reserach Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 89/903 (3) Status: Ongoing

(4) Title: Evaluation of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated. Protocol B: Continued Assessment of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated, Lot C-84-6, TSI-GSD 205 as a Booster in At-Risk Personnel, IND 914

(5) Start Date: Unknown (6) Est Compl Date: Ongoing

(7) Principal Investigator: Gerald G. Mindrum, COL, MC (8) Facility: FAMC US Army Health Clinic DPG

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 35
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached. No new enrollments for this reporting period.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 91/902 (3) Status: Ongoing

(4) Title: Administration of Equine Heptavalent Antitoxin for Therapy of Suspected Botulism Intoxication

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Gerald G. Mindrum, COL, MC

(8) Facility: USAMRIID
CDC

(9) Dept/Svc:

(10) Associate Investigators:

Shannon Harrison, COL, MC,
Ft. Sam Houston, TX

(11) Key Words:
antitoxin
botulism

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 21
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The principle objective is to provide the depeciated botulinum antitoxin to individuals who may be exposed to botulinal toxins by foodborne, parenteral, or aerosol routes. A secondary objective is the collection of information regarding reactogenicity and efficacy of the product in humans.

(16) Technical Approach: Per Medical Research Institute of Infectious Diseases protocol IND 3703.

(17) Progress: Protocol recently approved by OTSG. One patient enrolled.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 92/900A (3) Status: Terminated

(4) Title: Use of Goats for Training in Advanced Trauma Life Support

(5) Start Date: 1993 (6) Est Compl Date:

(7) Principal Investigator: Scott A. Crollard, MAJ, MC (8) Facility: FAMC Ft. Carson MEDDAC

(9) Dept of SUR/ (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____22_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To conduct realistic training in procedurs selected by the Committee on Trauma, American College of Surgeons, for the Advance Trauma Life Support Course.

(16) Technical Approach: In accordance with the ATLS Instructors Manual.

(17) Progress: 84 individuals trained; 252 hours of training.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 3 Mar 94 (2) Protocol #: 92/901 (3) Status: Ongoing

(4) Title: Army Pregnancy Study

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator:
Joseph Creedon, Jr., CPT, MC

(8) Facility: FAMC
Ft. Carson, CO
Evans Army Community Hospital

(9) Dept of Occupational Health

(10) Associate Investigators

(11) Key Words:
reproductive outcome
occupational factors

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___MAY____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of this current investigation is to attempt to quantify risk to the offspring of female soldiers in teh U.S. Army by CMF and MOS for the following outcomes: spontaneous abortions, ectopic pregnancies, intrauterine fetal demise, preterm birth, low birth weight infant, preterm and low birth weight infant, and congenital abnormalities.

(16) Technical Approach: Initially to be conducted as a pilot study at Evans ACH. Multi-center demographic questionnaire will be performed on study group comprised of female soldiers and the comparison group will consist of wives of soldiers.

(17) Progress: The pilot phase of this study is complete. Amendments to the protocol, questionnaire and consent form were reviewed and approved by the IRC at the 2 Mar 93 meeting. The protocol will be sent to associate investigators at other sites.

FY94: As of 3 Mar 94, 1196 subjects have been enrolled which include 371 active duty soldiers, 751 spouses, 66 daughters and 8 women classified as other. This population represents a total of 1179.05

person years of occupational exposure in the soldier populations and 780.25 person years of occupational exposure i the non soldier population. A total of 503 outcomes have been obtained of which 411 were live births. Currently no statistically significant associations have been noted regarding birth weight and eligibility status (p+0.373), soldier vs. spous vs. daughter vs other. Conversely, black race when compared to the non-black cohort has been associated with 228 gm statistically significant lower mean birth weight (2974 gm vs. 3202 gm, p=0.003).

A nested case control study has bee performed on some of the soldier data. This study has revealed that the overall unplanned pregnancy rate for the active duty soldiers enrolled was 30.5% (113/371), however, the unplanned pregnancy rate for female soldiers residing in the barracks was 77.9% (88/113). All confidence limits were calculated at 95%. The odds ratio for pregnant female soldiers who live in the barracks for unplanned pregnancy was 3.41 (1.99, 5.89) and the odds ratio for pregnant female soldiers never having taken oral contraceptives was 4.17 (2.27, 4.97). This early data has helped to identify the active duty soldier population aa a risk group to target for pregnancy prevention. The unplanned pregnancy rate is felt to substantially impact upon readiness, man-hours lost to the soldier's unit, and the dollar cost for medical care.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 92/904 (3) Status: Completed

(4) Title: The Effect of Placing Infants in Bed Awake at Night on Infant's Sleep Pattern.

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator:
Helen Cook, MAJ, AN

(8) Facility:
Evans Army Community Hospital
Ft. Carson, CO 80913

(9) Dept of Nursing

(10) Associate Investigators
Ruth Crutchfield, PNP
Shirley Stewart, PNP
Carol Wetzig, PNP

(11) Key Words:
infants
sleep pattern

(12) Accumulative MEDCASE:*
*Refer to Unit Summary Sheet of this Report.

(13) Est Accum OMA Cost:*

(14) a. Date, Latest IRC Review: ___July___ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____52_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Teaching the infant at an eraly age to sleep through the night will reduce family stress and possibley reduce child abuse.

(16) Technical Approach: Pilot project using 25 subjects for control and intervention groups.

(17) Progress: Started enrolling people once they had compiled a week of sleep data (baseline) on their child, which cut down on the number of drop outs. If person returns in one week to sign the consent form the majority will stay with the collection phase. The summer is a slower time period for well babies so we would like to request another year's collection time to get 25 members in each group (control and treatment).

FY94: PI PCS'd to Ft. Lewis, WA. However, data collection was completed on 25 treatment and 27 control. Data is being analyzed.

Publications and Presentations: Presented, May 1993 for Nursing Research Symposium sponsored jointly by FAMC and EACH. Focus: Trials and joys of designing and collecting data for research.

Detail Summary Sheet

(1) Date: 4 Jan 94 (2) Protocol #: 93/900 (3) Status: Ongoing

(4) Title: Fort Riley Health Promotion Intervention Project

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Steven Finder, LTC, MC

(8) Facility:
MEDDAC, Ft. Riley, Ks

(9) FRIP

(10) Associate Investigators
SSG Henry Franco, LPN
Frances A. Bollitto, RN
Karen H. Grimes, RD
Melanie T. Richardson, MS
Lynda S. Colston, LPN
Rosita N. Aguigui

(11) Key Words:
health promotion
hospital costs

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
694 families, 1000+ individuals
d. Total Number of Subjects Enrolled to Date: 563 families
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Can a health prevention and promotion program reduce short-term direct hospital costs.

(16) Technical Approach: Three-arm multi-year study incorporating two study groups and a control group.

(17) Progress: Since Jan 93, the study has acquired a building, developed the intervention and study instruments and begun the intervention. Currently, the project is developing a hospital wide data base to track hopsital outpatient costs.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 5 Jul 94 (2) Protocol #: 93/901 (3) Status: Completed

(4) Title: Measurement of Isokinetic Forces of Elbow Flexors and Extensors - A Normative Study

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Mary Koch, MAJ, SP

(8) Facility: FAMC
General Leonard Wood Army Community Hospital

(9) Dept of PHYSICAL THERAPY

(10) Associate Investigators

(11) Key Words:
isokinetic exercise
elbow

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 38
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Unchanged from original protocol Aug 93.

(16) Technical Approach: Unchanged from original protocol Aug 93.

(17) Progress: (only approved August 93), data collection is ongoing since 20 Aug 93. FY94: To date 38 subjects enrolled. Data Collection is still ongoing. Anticipate closeout of project at end of July 94.

Publications and Presentations: None

Detail Summary Sheet

(1) Date: 6 Sep 94 (2) Protocol #: 93/902 (3) Status: Ongoing

(4) Title: Epidemiology of Prescribed Medication Use Among Active-duty Troops, Retired Soldiers and Their Families

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Lisa Johnson, MAJ, MS

(8) Facility:
Irwin Army Community Hospital
Ft. Riley, Ks
66442-5037

(9) Pharmacy Service

(10) Associate Investigators
MAJ John Grabenstein
LTC Roger Potyk

(11) Key Words:
epidemiology, medication

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To quantify use of prescribed medications among active-duty soldiers, retired soldiers, and their families at representative Army posts.

(16) Technical Approach: Descriptive report of the incidence and prevalence of use of prescription medications among various groups and subgroups during a 9-month interval.

(17) Progress: None, recently approved study.

FY94: To date approximately 200,000 prescriptions have been analyzed. The most frequent generic chemical entites dispensed were ibuprofen (3.9% of prescriptions filled), acetaminophen (3.4%), estrogen-progestoge combinations (3.0%), albuterol (2.2%), nifedipine (2.1%), and clotrimazole (2.0%). The most common therapeutic classes dispensed were oral antibiotics (10.8% of prescriptions), nonsteroidal anti-inflammatory drugs (8.8%), and contraceptive drugs (3.8%). The most common presumptive diagnostic groups were infectious disease (17.0%), respiratory (16.5%), cardiovascular (15.5%), and musculo-skeletal (10.1%).

Publications and Presentations: None

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-900

Assessment of Risk Factors for HIV Infection Among Active Duty U.S. Military Personnel with Documented Recent HIV-Antibody Seroconversion - Phase II

START DATE: Jan 94 EST COMP DATE: Jan 97 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Paula Underwood, MAJ, MC

FACILITY/DEPT/SVC: Fort Carson/Evans ACH/Public Health and Safety

ASSOCIATE INVESTIGATORS: Annelle Price, RN

PERIODIC REVIEW DATE: Dec 93 REVIEW RESULTS: Continue
FUNDING: MRDC, HMJ
GIFTS: NA

KEY WORDS: HIV

OBJECTIVE: To determine specific factors that are associated with becoming infected with HIV.

TECHNICAL APPROACH: Computer driven survey using questionnaires, estimate 3 cases and 6 controls per year, per WRAIR protocol.

PROGRESS:
Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Minor revisions made to original protocol by MRDC, HMJ. Revised protocol submitted to IRC, FAMC, 2 Sep 94.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-901

Learning and Attention of 5- to 12-Month-Old Infants Who had Hyperbilirubinemia or Polycythemia in the Newborn Period

START DATE: Feb 94 EST COMP DATE: Jun 94 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Ruth Crutchfield, Nurse Practitioner, DAC

FACILITY/DEPT/SVC: Evans ACH/Ped/Fort Carson

ASSOCIATE INVESTIGATORS: Catherine Weir, PhD, Dept of Psychology, Colorado College, Colo Spg

PERIODIC REVIEW DATE: Feb 94 REVIEW RESULTS: Continue
FUNDING: NA
GIFTS: NA

KEY WORDS: hyperbilirubinemia, polycythemia, newborns

OBJECTIVE: The study aims to examine the cognitive development of babies with different neonatal histories.

TECHNICAL APPROACH: Three groups will be considered with 30 subjects in each group: 1) infants who had neonatal hyperbilirubinemia; 2) infants who had polycythemia; 3) infants who did not have any perinatal complications. Infants will be observed for their reaction to habituation and learning tasks.

PROGRESS:
Number of subjects enrolled to date: 50
Number of subjects enrolled for reporting period: 50
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: Between 16 Mar 94 and 16 Sep 94, 50 infants have been tested. Of these 4 failed to complete both tasks (8%), and there were equipment failures for 7 others (14%). This leaves 39 infants in the sample.

PUBLICATIONS: None.

PRESENTATIONS: None.

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-902

Effect of Staged Versus Rapid Deployment to Moderate and High Terrestrial Elevations on Physical Work Performance in MOPP and Acute Phase of Altitude Acclimatization

START DATE: July 94 EST COMP DATE: July 94 STATUS: Completed

PRINCIPAL INVESTIGATOR: Steven Muza, PhD, DAC

FACILITY/DEPT/SVC: Pikes Peak/USARIEM/Alt Phys

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: Jun 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: altitude, physiology, acclimatization

OBJECTIVE: Assess the interaction of moderate and high terrestrial elevations with the wear of MOPP IV ensemble on: 1) physical work performance of selected military tasks; 2) the associated responses of the ventilatory and cardiovascular systems, and; 3) perception of exertion and respiratory sensations.

TECHNICAL APPROACH: Test of ten lowlanders will be compared to test of ten high-altitude acclimatized subjects.

PROGRESS:

Number of subjects enrolled to date: 10
Number of subjects enrolled for reporting period: 10
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): NA

Summary of prior and current progress: Volunteers selected at Fort Carson completed the tests conducted on Pikes Peak during the month of July, 1994.

PUBLICATIONS: NA

PRESENTATIONS: NA

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 91/950A (3) Status: Terminated

(4) Title: Postgraduate Course on Obstetric, Neonatal, and Gynecologic Care: Resuscitation of the Newborn Utilizing the Ferret Model

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Thomas Harris, MD

(8) Facility: FAMC
Neonatology Associates, Ltd.
Phoenix, AZ 85013

(9) Dept/Svc: Pediatrics/Newborn

(10) Associate Investigators:
Beverly Anderson, LTC, MC

(11) Key Words:
training
ferret model, resuscitation

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____57_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To enable new officers of the Indian Health Service to become proficient in the life-saving technique of endotracheal intubation used in neonatal resuscitation.

(16) Technical Approach: Endotracheal intubation of anesthetized ferrets under supervision of certified animal technicians.

(17) Progress: All trainees have become proficient in the procedure by the end of the 1-2 hour workshop.

Publications and Presentations: None.

Detail Summary Sheet

(1) Date: 30 Sep 94 (2) Protocol #: 93/950A (3) Status:Terminated

(4) Title: Study to Determine the Effectiveness of the Permethrin Insecticide, PCC-331, Placed in Bait Stations, to Control Flea Vectors of Plague on Tree Squirrels

(5) Start Date: 1993 (6) Est Compl Date: 1994

(7) Principal Investigator:
Ted Davis,

(8) Facility: FAMC
Colorado Dept of Health

(9) Dept of USAEHA-W

(10) Associate Investigators
Frederick J. Harrison, Jr.

(11) Key Words:
plague, fox squirrel

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:___42_____
d. Total Number of Subjects Enrolled to Date:_____42_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if a selected insecticide, placed into bait stations, will kill fleas on squirrels thereby reducing the threat of plague in the community. This study is in response to the current plague epizootics among squirrels along the front range of Colorado, in particular Boulder, Colorado Springs, and Pueblo.

(16) Technical Approach: Squirrels will be live trapped, anesthetized, combed for fleas, ear tagged for identification, and released at the capture site. Bait stations equipped with insecticide impregnated rings at each end will be used to passively apply a small amount of material to the squirrel as it passes into the tube. Thirty days following the baiting, squirrels will again be captured and combed for fleas to determine the effectiveness of the insecticide.

(17) Progress: Low flea counts in summer 1993 resulted in insufficient data to evaluate the insecticide. Repeat field trials in fall 1994.

Publications and Presentations: None

FY94 DETAIL SUMMARY SHEET FOR PROTOCOL 94-950A

Postgraduate Course on Obstetric, Neonatal and Gynecologic Care: Resuscitation of the Newborn Utilizing the Ferret Model (Mustela putorius furo)

START DATE: Aug 94 EST COMP DATE: Aug 96 STATUS: Ongoing

PRINCIPAL INVESTIGATOR: Thomas Harris, MD, NA

FACILITY/DEPT/SVC: FAMC/NA/NA

ASSOCIATE INVESTIGATORS: NA

PERIODIC REVIEW DATE: Aug 94 REVIEW RESULTS: Approved
FUNDING: NA
GIFTS: NA

KEY WORDS: training

OBJECTIVE: To enable new officers of the Indian Health Service to become proficient in the life-saving technique of endotracheal intubation used in neonatal resuscitation.

TECHNICAL APPROACH: Endotracheal intubation of anesthetized ferrets under supervision of certified animal technicians.

PROGRESS:
Number of subjects enrolled to date: 13
Number of subjects enrolled for reporting period: 13
Nature and Extent of Significant Adverse Events (reported to the FDA or sponsor): None.

Summary of prior and current progress: All trainees were proficient in the procedure by the end of the one-hour workshop.

PUBLICATIONS: None

PRESENTATIONS: None

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INDEX OF KEY WORDS

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